EXHIBIT 1

TRANSCRIPT OF 2/15/2018 DEPOSITION OF MICHAEL MILLER, M.D.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEVADA

- - - - - - - - - - - - - - - X

AMARIN PHARMA, INC., et al.,	: Case No.: 2:16-CV-02525-MMD-NJK
Plaintiffs	:
vs.	: (Consolidated with
WEST-WARD PHARMACEUTICALS CORP., et al.,	: 2:16-CV-02562-MMD-NJK, 2:16-CV-02658-MMD-MJK,
Defendants.	: 2:17-CV-02641-RFB-GWF)

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[redacted]

Videotaped Deposition of MICHAEL MILLER, M.D.

Washington, D.C.

Thursday, February 15, 2018

8:03 a.m.

Job No. 225981

Pages: 1 - 272

Reported by: Dana C. Ryan, RPR, CRR

February 15, 2018
8:03 a.m.

Videotaped Deposition of MICHAEL MILLER, M.D., held at the law offices of Covington & Burling LLP, One City Center, 850 Tenth Street, Northwest, Washington, D.C., pursuant to the Federal Rules of Civil Procedure, before Dana C. Ryan, Registered Professional Reporter, Certified Realtime Reporter and Notary Public in and for the District of Columbia.

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFF:
MICHAEL N. KENNEDY, ESQ.
HAN PARK, ESQ.
Covington & Burling LLP
One City Center
850 Tenth Street, Northwest
Washington, D.C. 20001

ON BEHALF OF THE DEFENDANTS
WEST-WARD PHARMACEUTICALS CORP. AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED:
ALAN B. CLEMENT, ESQ.
Locke Lord LLP
Brookfield Place
200 Vesey Street, 20th Floor
New York, New York 10281

A P P E A R A N C E S C O N T I N U E D

ON BEHALF OF THE DEFENDANTS
DR. REDDY'S LABORATORIES, INC. AND
DR. REDDY'S LABORATORIES LIMITED:
CAROLINE SUN, ESQ.
Budd Larner, P.C.
150 John F. Kennedy Parkway
Short Hills, New Jersey 07078

ON BEHALF OF THE DEFENDANT
TEVA PHARMACEUTICALS USA INC.:
CHANDRIKA VIRA, ESQ.
Sterne, Kessler, Goldstein & Fox, P.L.L.C.
1100 New York Avenue, Northwest
Washington, D.C. 20005

A P P E A R A N C E S C O N T I N U E D

Also present:
Francis Solomon, Videographer
Jennifer Scarpati
Deepti Jain

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PROCEEDINGS

THE VIDEOGRAPHER: Good morning. This is tape number 1 in the videotape deposition of Dr. Michael Miller taken by counsel for the defendants in the matter of Amarin Pharmaceutical, Inc., et al., plaintiffs, versus West-Ward Pharmaceutical Corp., et al., defendants, in the United States District Court for the District of Nevada, case number 2:16-CV-02525-MMD-NJK.

This deposition is being held at the law office of Covington & Burling LLP on February 15th, 2018. My name is Solomon Francis from the firm of U.S. Legal Support. I'm the legal video specialist. The court reporter is Dana Ryan also of U.S. Legal Support.

We are on the record at 8:03 a.m.

At this time will counsel state their appearances and affiliations for the record.

(Counsel state appearances for the video record.)

THE VIDEOGRAPHER: At this time will the court reporter please swear the witness?

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MICHAEL MILLER, M.D.,

having been duly sworn or affirmed, was examined and did testify under oath as follows:

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THE VIDEOGRAPHER: Please proceed, Counsel.

EXAMINATION BY COUNSEL FOR THE DEFENDANTS WEST-WARD PHARMACEUTICALS CORP. AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED

BY MR. CLEMENT:

Q Good morning, Dr. Miller.

A Good morning.

Q My name is Alan Clement. I represent West-Ward Pharmaceuticals in this case, and we're going to have your deposition today.

Have you ever been deposed before?

A I have.

Q Okay. And in what type of case was that -- or how many -- let me ask this. How many times have you been deposed before?

A At least ten.

Q At least ten.

Were any of those in patent cases?

A One.

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Q One, okay.

And do you recall what case that was?

A The case was with pitavastatin or Livalo, so it was on behalf of Kowa Pharmaceuticals.

Q Kowa.

You worked with Dave Conklin and Kathleen Carr?

A I did.

Q Yeah, okay.

And were -- you were deposed in that case?

A Yes.

Q Okay. And that's a stat- -- that's a statin drug, pitavastatin?

A Correct.

Q Okay. And did you appear at trial in this case?

A I did.

Q And when was that trial?

A I believe it was January of 2017.

Q And Kowa was the brand pharmaceutical company; correct?

A That is correct.

Q They were the patent owner and Takeda

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is the brand?

A I believe so.

Q And do you recall what courtroom -- what court -- was that Delaware?

A It was in Manhattan.

Q Manhattan, okay.

Do you recall who the defendant was in that case?

A There were several, but I don't recall --

Q Okay.

A -- specifically.

Q That's fine.

Okay. And the other nine cases were not patent cases -- you said -- let me strike that.

You said at least ten times you've been deposed. You were -- I guess, you weren't quite sure, and I'm not trying to pin you down to a number.

So the other cases, other than the patent case, what type of cases were those?

A Primarily malpractice-related cases, and then I was also involved in a case for Pfizer.

Q And then you said a case for Pfizer,

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what type of case was the case for Pfizer?
A Okay. That was an MDL.
Q Okay. Was it a product liability-type case?
A Yeah. The -- the case centered around the development of diabetes amongst women.
Q And in the patent case, the pitavastatin case, were you testifying regarding infringement?
A Yeah -- yes.
Q What about validity or invalidity?
A Well, as I recall, I was asked to testify about the method that made the drug -- the compound unique in its class.
Q And what made the compound unique in its class?
A Well, there are several properties of pitavastatin both -- both from a chemical standpoint as well as a clinical standpoint that was associated with reduced side effects that may have been experienced by patients taking other medications --
Q So reduced --
A -- other statins.
Q -- reduced drug interactions?

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A That is correct.
Q Okay. And different from other statins, it would have reduced side effects; is that what you're --
A Correct.
Q -- saying?
Okay. All right. So you've been deposed before, so, I guess, you know kind of the drill here. I'm going to ask you a series of questions. You know nods of the head can't be recorded, so I'd ask for verbal responses, yes or no if it's a yes/no question.
A Yes.
Q Is that okay?
A Yes.
Q All right. And if you don't understand the question, please let me know and I'll try and rephrase.
A Thank you.
Q Okay. And is there any reason you can't answer the questions I have today truthfully?
A No.
Q Okay. You're not on any medications that would impair your ability to answer

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truthfully; correct?
A Correct.
Q Okay. All right. Let's mark the first exhibit.
(Miller Deposition Exhibit 1 was marked for identification and attached to the transcript.)
BY MR. CLEMENT:
Q Dr. Miller, what the court reporter has put before you -- and marked as Miller Exhibit 1, is a Defendant's Notice of Deposition of Dr. Michael Miller.
Have you ever seen this document before?
A (Witness reviews document.)
I'm not sure that I have.
Q Okay. How did you know to come here today?
A Well, I came here today because I've been working on this case with Covington.
Q And they informed you that your deposition was going to be today?
A That is correct.
Q Okay. You know, this is more a formal -- just, you know, take some of the mystery out of

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it, this is more of a formal document and why Covington told you -- I'll represent to you at least my belief. It's why Covington told you to appear here today, but that's fine you haven't seen the document.
Did you prepare for your deposition today?
A I did.
Q Okay. And about how long did you prepare for your deposition today?
A In terms of hours?
Q Days, hours.
A I don't have an exact number at this time.
Q Okay. Was it -- did you meet with counsel yesterday?
A I did.
Q How many times did you meet with counsel for prep -- for your deposition preparation?
A For the deposition preparation, I believed -- I believe that I met with counsel twice.
Q Twice, okay.
And when was that? One was yesterday;

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is that correct?
A One was yesterday.
Q And when was the other?
A Within the past two weeks.
Q And about -- within the past -- so the -- let's strike that.
So the first meeting, the one that was -- occurred other than yesterday, was that an in-person meeting or telephone?
A In person.
Q In person.
And that was at Covington's offices?
A That is correct.
Q And was that a full-day meeting?
A How do you define "full day"?
Q Eight hours.
A No.
Q Okay. Part of a day?
A That's correct.
Q Okay. Did it start in the morning?
A Yes.
Q Go through lunch?
A Yes.
Q And into the afternoon?
A Early to mid-afternoon.

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Q Okay. So six hours would be a reasonable estimate?
A Yes.
Q Did you review documents?
A Yes.
Q Do you recall what documents you reviewed?
A Primarily the documents related to this case.
Q Do you recall which ones?
A My declaration.
Q Any others?
A The patents, prosecution history.
Q All the prosecution histories or any one in particular?
A As it related to my declaration.
Q So in your exhibits to your declaration, you had excerpts from the '727 prosecution history and the '728 prosecution history.
Any -- did you review other -- other than those two, did you review prosecution histories?
A I would have to refer to my declaration to see which other patents I reviewed.

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Q Do you recall reviewing anything other than what was in your declaration in your meetings with Covington preparing for the deposition?
A I think I did.
Q Okay. Could you recall what documents those were?
A Again, I would have to review my declaration to see the documents.
Q Okay. So none come to mind as documents that you did not have as an exhibit to your declaration that you reviewed in preparation for your deposition?
A Well, I reviewed Wharton's deposition.
Q Okay. Did you review his report as well?
A I reviewed his declaration as well.
Q Declaration, thank you.
Okay. Do you recall any other documents not exhibits to your declaration --
A I don't recall.
Q -- that you reviewed?
Okay. And then yesterday you met with counsel, also?
A That is correct.
Q Okay. Who did you meet with yesterday?

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A I met with Mike Kennedy, Han, Megan Keane.
Q Anyone else?
A Joe was in the room.
Q Anyone else?
A I believe that's it.
Q Okay. And was yesterday a full day?
A Yesterday was a full day.
Q Okay. And, again, did you review any documents yesterday in preparation for today's deposition that were not exhibits to your declaration?
A I don't believe so.
Q Okay. But you might have -- did you review Wharton's deposition transcript yesterday?
A Minimally.
Q Okay. And what about his declaration -- his declaration?
A Minimally.
Q Okay. Do you recall how you became an expert in this case?
A I believe I was contacted by Covington sometime last summer.
Q Were you aware that there was a prior case involving the same drug between Amarin and

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defendants that was pending in New Jersey a few years ago?
A No.
Q So the first time you were contacted by Covington regarding working on a Vascepa litigation was last summer?
A That is correct.
Q And do you recall who contacted you?
A I don't.
Q Okay. Let's mark your declaration as Miller Exhibit 2.
(Miller Deposition Exhibit 2 was marked for identification and attached to the transcript.)
BY MR. CLEMENT:
Q And Dr. Miller, what I've put before you is a copy of your first declaration in this case without the exhibits.
Can you take a look at page 47 and confirm that's your signature?
A Yes, this is my signature.
Q And you signed that on November 1st, 2017?
A I did.
Q Do you know who wrote this declaration?

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A Well, the declaration was a collaborative effort between my attorneys and myself. The opinions in this declaration are mine.
Q Who typed it?
A I have no idea.
Q Okay. You did not type it?
A I did not type it.
Q Okay. So drafts went back and forth between you and counsel. You commented on it. And this is the final product, and it contains your opinions; right?
A That is correct.
Q Okay. Have you ever been involved in a -- do you under- -- well, strike that.
Do you understand that your declaration pertains to something called claim construction?
A Yes.
Q Okay. Have you ever been involved in a claim construction proceeding before?
A No.
Q No.
So you're -- in the pitavastatin case, you were not involved in the claim construction?
A Correct.

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Q Okay. Okay. And I think you say in this declaration, and correct me if I'm wrong, but you understand that all of the patents involved in this lawsuit except for one, the '594, they all share the same patent specification?
A Yes.
Q Okay. So it will be okay by you if when we refer to column and line numbers unless I indicate otherwise, I'm going to be referring to the '728 patent; is that okay?
A Yes.
Q Okay. And the last time you reviewed your declaration was yesterday?
A This morning.
Q This morning. Okay.
And in reviewing your declaration, did you note any corrections or revisions that you wanted to make?
A I don't believe so.
Q Okay.
MR. CLEMENT: All right. Let's mark as Miller Exhibit 3 a copy of the materials considered which was Exhibit 2 to your declaration.
(Miller Deposition Exhibit 3 was marked

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for identification and attached to the transcript.)
BY MR. CLEMENT:
Q Okay. Dr. Miller, can you confirm this is the materials you considered for your opening declaration?
A Yes.
Q And where did you get these materials?
A The majority of the materials were provided to me by my attorneys.
Q Okay. And did your counsel provide you any materials to look at that are not on this list?
A I don't believe so.
Q Did you do any research to find materials?
A I didn't do additional research beyond what appears here.
Q So all of the materials that are in these materials considered Miller Exhibit 3 came from counsel?
A Well, I was familiar with a number of the publications prior to counsel providing them to me.
Q Did you instruct counsel to find those

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for you or they just happened to show up from counsel?

A They were provided by counsel, but, again, I was familiar with many of the publications.

Q All right. Understood. And that's -- that's great. That's fine.

I just want to understand that all the materials here -- did you ask for counsel to provide you with any of those materials?

MR. KENNEDY: Objection to form.

THE WITNESS: (Reviews document.)

There might have been one or two publications, but I -- I don't recall specifically which ones.

BY MR. CLEMENT:

Q And looking at that list doesn't refresh your recollection?

A Bays, Davidson and Jacobson are manuscripts that I'm familiar with, but, again, I don't recall whether I specifically suggested one or more of those.

Q Okay. And when you referred to Bays just then, that was number 34?

A Thirty-four and 35. Davidson is 36 --

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Q Okay.

A -- and Jacobson is 37.

Q Okay. But you don't recall whether or not those were provided to you by counsel or you asked for them; is that fair?

A That's fair.

Q Great.

MR. CLEMENT: Okay. Let's mark as the next exhibit a copy of your reply declaration as Miller 4.

(Miller Deposition Exhibit 4 was marked for identification and attached to the transcript.)

BY MR. CLEMENT:

Q And, Dr. Miller, if you'll take a quick look through that, and can you identify that document for the record?

A (Witness reviews document.)

I can.

Q And what is Miller Exhibit 4?

A It is a reply declaration.

Q And is that your signature on page 9 of that declaration?

A Yes, it is.

Q And you signed that on February 2nd, 2018?

A That is correct.

Q With this declaration, you did -- you didn't include a list of additional materials considered; correct?

A (Witness reviews document.)

That is correct.

Q Did you consider additional materials in preparing your reply -- reply declaration in addition to what you considered for your initial declaration?

A I don't believe that I did.

Q Well, you would have considered the Wharton declaration; right?

A Right. This is -- this is a reply to Wharton.

Q Okay. And you would have considered the Wharton transcript as well -- his deposition transcript?

A I am not sure that the Wharton transcript was part of this response. I believe it was in response to his declaration.

Q Okay. So you don't recall if you saw the Wharton deposition transcript before February 2nd?

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A I don't recall.

Q Okay. And did you consider the exhibits that were attached to Dr. Wharton's declaration?

A I believe I reviewed many of them.

Q Okay. Do you recall any other materials that you considered for your reply declaration other than your materials considered in your first declaration and the Wharton declaration and Wharton exhibits?

A Yeah, I don't believe so.

Q Okay. And your declaration -- this reply declaration, Miller Exhibit 4 --

A Yes.

Q -- you only opine on two terms; correct?

A I only opine on two terms, but I believe I make a statement specifically on page 2, and that would be under number 2 where I say, I have not responded to every statement in the Wharton declaration in this reply declaration. If I have not responded to a particular statement, it should not be assumed that I agree with Dr. Wharton's opinions.

Q Okay. But the opinions you provided

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related to two terms; correct?
A In this reply declaration, that is correct.
Q Okay. And that was the "concurrent/concomitant lipid-altering therapy" term; that would be one of them?
A That is correct.
Q And then also the "without substantially increasing LDL-C" terms; right?
A That is correct.
Q And why did you only choose to put in your reply declaration responses regarding those two terms?
A To provide clarification.
Q And you didn't think any further clarification was required for the other terms that Dr. Wharton opined on?
A Well, not necessarily, but this -- these were the most important claim terms that I wanted to comment on.
Q Okay. And you didn't feel the need to comment on the other terms that Dr. Wharton opined on; correct?
A That's correct.
Q Do you know how these two terms were

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selected? Did you select these two terms or did counsel?
A I did not select the claim terms.
Q So counsel asked you to opine further on "concurrent/concomitant lipid-altering therapy" and the "without substantially increasing" terms?
MR. KENNEDY: I caution the witness -- the witness can answer that question yes or no, but I caution the witness to avoid revealing the substance of communications he may have had with counsel.
BY MR. CLEMENT:
Q Yes or no is fine.
A Can you repeat the question, please?
MR. CLEMENT: Can you read that back?
(The Record was read as requested.)
THE WITNESS: Yes.
BY MR. CLEMENT:
Q And when was the last time you reviewed your reply declaration, Miller 4?
A Within the past 24 hours.
Q And, again, do you have any corrections or revisions you want to make on this exhibit?
A I don't believe so.
Q And, again, how was this document

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prepared? Was this, again, a collaborative effort similar to the first declaration?
A Yes.
Q Did you know Amarin Pharmaceuticals before you became involved in this case?
A I did.
Q And how did you know Amarin Pharmaceuticals before coming -- becoming involved in this case?
A They make Vascepa.
Q Okay. Any other way?
A They contacted me to serve on the steering committee for a clinical outcome study.
Q Any other ways?
A That was our initial -- that was how we made contact.
Q Okay. But did they -- have you been involved with Amarin other than -- and outside the scope of this case, have you been involved with Amarin other than as the steering committee on a clinical outcome study?
A Yes.
Q In what way or ways?
A They -- they asked me to give a presentation at the EMDAC meeting on

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triglycerides.
Q Any other ways?
A I advise them.
Q So you serve as a consultant for them?
A Yes, I serve as a consultant primarily as it relates to REDUCE-IT.
Q Is REDUCE-IT different than the clinical outcome study you referred to?
A That is the clinical outcome study.
Q And you say "primarily," you consult with them primarily as to REDUCE-IT.
Do you consult with them as to other?
A I've worked with them to provide training for physicians.
Q And can you be a little bit more specific? How do you work with them to provide training for physicians?
A They -- they have a -- as with other pharmaceutical companies, they have a -- a platform where potential speakers will discuss in a disease-management-fashion triglyceride lowering, the importance of triglycerides, and I've helped to build on that foundation.
Q So when you say platform for speakers, are you talking about a conference?

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A It -- it -- it's really more for teaching physicians about management of triglycerides. So teaching the physicians who will go out and perform these activities.

Q Right.

But, I guess --

A So I don't -- I don't -- I don't speak for Amarin, but I've advised them on teaching other physicians.

Q Okay. So you were -- how they would go and teach other physicians.

Is it for their sales reps? I mean, I'm just trying to understand.

A No, it's other physicians in -- in the field and essentially providing educational information.

Q So is this something that takes place at Amarin's facilities, or is it at a --

A Does not take place --

Q -- different location?

A Does not take place at Amarin's facilities.

Q Okay. Does this take place off-site somewhere -- some -- give me -- can you -- I guess -- strike that.

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Can you give me an example of where this would take place?

A Yeah, it takes place -- it's basically -- it could take place at a -- at an outside venue.

Q Uh-huh.

Do you recall any outside venues where it did take place?

A There was a conference that took place in California.

Q Okay. Do you recall when that was and where in California?

A That was about a year ago.

Q And where in California?

A San Diego.

Q Okay. Can you recall any other examples of these meetings that took place at outside venues?

A There was one in Florida.

Q Any others?

A That's it.

Q Okay. And where in Florida and when?

A South Florida.

Q Okay. And do --

A Within --

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Q -- you recall when?

A Within the last six months.

Q And the attendees at these meetings are just you and Amarin or are other people attending?

A The attendees at these meetings are physicians, generally, who are interested in treating lipid disorders. Many of them are certified by the National Lipid Association.

So these are individuals who have familiarity and are accustomed to seeing patients with lipid disorders.

Q And do you speak at these -- I guess I'm a little con- -- I'm trying to understand better. I can't recall. Did you say you -- do you speak to these physicians at these outside venues we just discussed?

A I speak to the physicians; that is correct.

Q Are you on, like, a panel?

A Yes.

Q Okay. Do you recall who else was on the panels with you? Let's take the California one.

A There -- there were a few that I -- I'd have to go through the NLA review to take -- take

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a look at that.

Q Okay. Do you recall who was in the Florida one -- six months ago?

A Again, I would have to look at the review.

Q Okay. You also said you gave a presentation to EMDAC as part of some of the other consulting work you do for Amarin; is that correct?

A That was about five years ago.

Q What is EMDAC?

A It is a -- an FDA endocrinology committee that -- that is assigned to review, I guess, companies who are looking to seek a change either in -- a new label or a change in a label, an indication for their compound.

Q Okay. So we've talked about your serving on the steering committee for the REDUCE-IT study; right?

A Yes.

Q We talked about the EMDAC -- EMDAC meeting that you attended and also the California conference and Florida conference.

A Correct.

Q Any other work for Amarin?

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A No.
Q Okay. Do you get paid for your work on the steering committee?
A Yes.
Q Do you get paid for your work at -- at the EMDAC meeting?
A I did, yes.
Q And do you get paid for your work when you attend -- attended the California -- on the panel at the California conference?
A Yes.
Q And also at the Florida conference?
A Yes.
Q Do you recall about how much you've been paid by Amarin for this work?
A I don't.
Q Okay. So when you're at these conferences, do you advise the physicians to prescribe drugs -- any drugs?
A I don't.
Q You don't advise them to prescribe Vascepa if the patient presents in a certain manner?
A I don't.
Q Okay. Do you present on -- I guess --

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can you give me an example of what you present on?
A Sure.
I -- at the most recent meeting, I talked about treating high risk patients and the areas that have not received attention as much. So the talk focused on LDL centricity, that is, treatment of patients with high LDL specifically.
Another part of the treatment -- another part focused on treatment of inflammation; another part focused on diabetes.
Q When you say "LDL centricity," what do you mean by centricity?
A Yeah. So there are some that believe that all you need to do to treat a patient with heart disease with respect to treatment of lipid disorders -- lipid disorders, quote/unquote, is to put them on a statin to lower LDL and nothing else really matters. So it is an LDL-centric focus.
Q Gotcha. Okay. Thank you.
MR. CLEMENT: Okay. Let's mark the next exhibit which is a copy of your CV, and that's Miller 5; correct?
(Miller Deposition Exhibit 5 was marked for identification and attached to the transcript.)

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BY MR. CLEMENT:
Q And Dr. Miller, what the court reporter has placed in front of you I'll represent to you is a copy of the CV that you attached to your initial declaration in this case as Exhibit 1.
Can you just take a quick look and --
A Well, I believe it was Exhibit 5.
Q Right. It is Exhibit 5, but I believe it was Exhibit 1 to your declaration. It is Exhibit 5 here, yes.
A Got it.
Q I think we're going to get a little confused with the exhibit numbers.
A (Witness reviews document.)
Q Okay. Do you know when this is up-to-date as of -- as of when?
A It says November 2017.
Q Okay. Is there any additions or revisions?
A I think paper 160 has been published.
Q And what page is that on?
A That is page 35.
Q Okay. Any other revisions or supplementations?
A No, I don't believe so.

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Q Okay. If you'll turn to page 7 of this Miller Exhibit 5, you have there in 2012 an entry saying that you were on the international steering committee, Amarin: REDUCE-IT trial; correct?
A That's correct.
Q Okay. And that's what we talked about earlier?
A Yes.
Q Okay. And that was the clinical outcomes -- you referred to it as the clinical outcomes trial?
A Yes.
Q And what was that clinical trial about?
A Well, the -- the trial is still ongoing, and it's about examining whether patients that have hypertriglyceridemia with cardiovascular disease may reduce their risk with ethyl eicosapentaenoic.
MR. CLEMENT: We'll get you the spellings after.
BY MR. CLEMENT:
Q Is that -- are you still serving on that steering committee then?
A I am.
Q How -- how -- I guess, how much work

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does that involve? I mean, how -- in the last 12 months, how much time have you spent?

A We have teleconferences quarterly.

Q And you get paid for that work; correct?

A I do.

Q Do you recall how much?

A I don't, but it's -- it's modest.

Q And you've been serving on this REDUCE-IT steering committee since 2012?

A Yes.

Q And what does it -- I guess, what do you do as a member of the steering committee for the REDUCE-IT trial?

REDACTED

Q Okay. And -- is that -- you're still discussing that in steering committee meetings today or has it evolved over the -- what is it -- five or six years that you've been involved?

REDACTED

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REDACTED

MR. KENNEDY: Let me just state I'd like a -- if you're going to get deeper into it, I would like a chance to consult with my client about the exact contours of his confidentiality obligation. Sitting here today, I'm not sure it's covered by the litigation protective order.

MR. CLEMENT: That's fair. I don't think I'm going to get too deep into it. I just . . .

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MR. KENNEDY: Okay.

BY MR. CLEMENT:

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Q What does retention mean?

A Retention is -- is keeping or trying to maintain a subject in a clinical trial. What sometimes happens is patients may move, so we need to try to find another site for them. Things happen.

Q Uh-huh.

A So we try to maintain as many of our patients in the study until trial end.

Q Okay.

MR. CLEMENT: Let's mark as the next exhibit Miller 6, a copy of some email correspondence.

(Miller Deposition Exhibit 6 was marked for identification and attached to the transcript.)

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BY MR. CLEMENT:

Q Dr. Miller, I guess, have you ever seen this document before?

A It looks like I have.

Q And would you agree with me that it's a copy of some email correspondence between you and Paresh Soni?

A Correct.

Q And there's three emails on the page?

A Yes.

Q Who is Paresh Soni?

A Paresh Soni was -- is a physician who worked with Amarin and -- on -- on this compound and was involved in -- in the REDUCE-IT clinical trial.

Q Now, this is dated 2010; right?

A Correct.

Q So were you working on the REDUCE-IT trial before you were a member of the steering committee?

A No. No, I -- the -- the -- the -- the basic premise of this email was when I was originally contacted by Paresh, I was involved in -- in writing an American Heart Association statement, and, so, it was unclear whether or not

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I could participate in -- in -- in working with -- on this committee.

So I had to go through my channels at the American Heart Association as well as the National Institutes of Health, and as stated in that March 4, 2010 email, that I had been cleared to -- to work with Paresh and the Amarin team.

Q Okay. So this was before you were on the REDUCE-IT steering committee; right?

A Correct.

Q And the outcome study that is referred to in the very bottom email, that would be the REDUCE-IT study?

A That is correct.

Q And in the top email Paresh says the first step is to execute the consulting agreement.

Do you see that?

A I do.

Q Do you recall executing the consulting agreement?

A I -- I must have.

Q Okay. And would that have been pre-serving on this steering committee for REDUCE-IT?

A Yes.

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Q Do you recall -- have you got paid for that consultant -- consultancy?

A Well, I've been paid. It's -- it's been the same agreement once I entered into the REDUCE-IT team or I should say steering committee.

Q Okay.

MR. CLEMENT: Let's mark the next exhibit. It's Miller 7.

(Miller Deposition Exhibit 7 was marked for identification and attached to the transcript.)

BY MR. CLEMENT:

Q And, Dr. Miller, I put some draft notes dated March 24, 2010, in front of you.

Have you ever seen these before?

A I don't recall.

Q Do you see the header for the exhibit, Miller 7? It says, Meeting with Michael Miller - University of Maryland School of Medicine?

A Yes.

Q And attendees M. Miller, P. Soni, B. Stirtan, and R. Braeckman?

A Yes.

Q That Michael Miller is you; right?

A That is me.

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Q Okay. Do you know who B. Stirtan is?

A I believe he worked with Amarin at that time.

Q And R. Braeckman?

A Yeah, that's Rene Braeckman. He and Paresh were -- were, I believe, on the invention of -- of many if not all of the patents.

Q Do you consider them experts in the field, Paresh and Rene Braeckman?

A Well, I consider them experts with respect to this particular compound, but if you could clarify what you mean by "experts" -- in what field.

Q Lipidology.

A Yeah, Paresh, I believe, was an M.D. Ph.D., so I -- but I'm not sure his clinical involvement. But -- but certainly he had a pretty good knowledge base. If he was not seeing patients, then I would -- I would think that he would consult with those that do, same with Rene.

Q Would you consider them -- I guess, in this case you recall you gave a definition of a person of ordinary skill in the art.

A (Witness nods head.)

Q Would you consider Paresh Soni to meet

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that definition?

MR. KENNEDY: Objection to form.

THE WITNESS: I don't know that I would.

BY MR. CLEMENT:

Q What about Rene Braeckman?

A I don't --

MR. KENNEDY: Same objection.

THE WITNESS: I don't know that I would.

BY MR. CLEMENT:

Q Okay. Why don't you know that you would?

A Well, because in my opinion a person of ordinary skill in the art as it relates to this particular field is a clinician who has pretty extensive experience in treating lipid disorders, and I -- I don't know the extent to which either of these individuals do.

Q Okay. And when you say "a person of ordinary skill in the art as it relates to this particular field," how do you define that field?

A The field of very high triglycerides; that's VHTG. These are triglycerides at or exceeding 500 milligrams per deciliter -- to

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distinguish it from patients that come in after a cardiac event that a cardiologist will prescribe a statin for.

Q Okay. In this email he talks about a -- you were not able to join Amarin at a February 27th ad board meeting.

Do you see that?

A Yes.

Q Do you know what an ad board meeting is?

A I don't know how it was used within this context. Ad board meetings can mean a lot of things. It can mean anything from putting together the clinical trial for all I know.

Q Do you recall being on an ad board for Amarin?

A Well, as I said, I -- serving -- I would view myself as serving in the capacity of an advisor by virtue of being on the steering committee for REDUCE-IT. That would constitute advising.

So, yes, ad board could be used interchangeably.

Q Okay. Great.

And then they -- it looks like here

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that they did consult with you on March 24th even though you weren't able to join that February 27th meeting?

A I believe they came to Baltimore.

Q So you recall that meeting?

A I -- I -- I do because we had -- they also met with a colleague of mine who then died tragically subsequently. It was very unfortunate.

Q Sorry to hear that.

And it says P. Soni presented the ad board slide deck and Rene Braeckman reviewed the outcome study synopsis.

Do you remember -- do you have a recollection of what that ad board slide deck was?

A I -- I have no idea. What -- what I do recall is we discussed the REDUCE-IT study.

Q Okay. Now, they also talk here under the general comments about a GSK outcome study.

Do you see that?

A I do.

Q Is that a different outcome study?

A So GSK was in the process of putting together an outcome study with Lovaza.

Q And GSK would be GlaxoSmithKline?

A That is correct.

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Q So that would be a different outcome study than the REDUCE-IT?

A Yes.

Q They also refer here to a Roche: dal-OUTCOMES.

Do you know what that is?

A I do.

Q What is that?

A Dal-OUTCOMES was a clinical outcome study looking at cholesteryl ester transfer protein or or CETP inhibitor that at that time was ongoing.

Q And what about the AIM-HIGH study?

A The AIM-HIGH study was another clinical trial looking to determine if raising HDL with niacin on top of standard of care therapy that included statin therapy would reduce cardiovascular risk.

Q And then it refers to a Bill Stanley?

A This is my colleague who died.

Q Oh, okay.

Then the next category here is EPA versus DHA Discussion.

Do you see that?

A I do.

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Q Was that something you were involved in?

A I don't recall -- we may have had discussions about it, but -- and I -- I remember that Martek produced DHA, but I don't recall much more beyond that.

Q And it says here, Thoughts on MOA for LDL increase by DHA.

Do you have any -- do you have an understanding of what MOA means?

A Mechanism of action.

Q Okay. Then the next part of the email talks about the AMR101 outcome study considerations.

A I see that.

Q What -- do you know what AMR101 is?

A That's the ethyl eicosapentaenoic. That is the compound that was used before it became Vascepa.

Q Okay. Can we say icosapent to make it easier for the court reporter?

A Sure.

Q Okay. Then it talks about some inclusion criteria?

A Yes.

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Q Is that something you talk about when you're on the recruitment phase on the steering committee as what patients to include, what inclusion criteria to have?
A This actually proceeded that, so this was a discussion as to what the entry criteria should be when the study was formalized.
Q Okay. Were you involved in these discussions on what the inclusion criteria should be?
A I think they asked my -- I'm presuming that they asked my opinion back -- as these notes relate to --
Q Uh-huh.
A -- but beyond that I -- I don't recall.
Q And do you see under the TG entry level there's a little Roman numeral II?
A Yes.
Q And it talks about a 15 percent leeway in triglyceride measure to enroll patients at either end of the range?
A Yes.
Q I guess -- do you know what that 15 percent refers to?
A Variability.

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Q But, so, was that 15 percent above or below 500?
A Either -- either way.
Q Either way.
So it could be 15 percent above 500?
A I think it was at the lower limit. The discussion was more focusing on 150.
Q Okay. So that was 15 percent above or below the 150?
A I believe so.
Q Not the 500?
A No.
Q Going down to the risk factors, do you see there's a reference to post-ACS patients?
A Yes.
Q Do you know what that refers to?
A A post-ACS is after an acute coronary syndrome.
Q Then if we turn down to fibrates at the bottom. It says, Fibrates are in trouble except for high TG, low HDL population.
A Yes.
Q Do you know what that refers to?
A It -- it refers to the clinical trials that had looked at fibrates and found that by and

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large the study was null, the clinical trial was null, with the exception of the hypertriglyceridemia, low HDL subgroup.
Q And there it was shown to be effective?
A These were post hoc analyses, so they're what we refer to as hypothesis generating. And, therefore, it wasn't shown because the study wasn't designed to specifically evaluate it, but it raised the suggestion that if you focused another trial on a patient population with high TG, for example, that you may have a different outcome.
Q Different outcome meaning it would have been effective?
A Well, we don't know.
Q Right. But that would have been the hypothesis?
A That's why Amarin stepped up to the plate to do the trial.
Q The --
A First --
Q -- trial on fibrates?
A The first -- Amarin was the first company to do a clinical trial specifically evaluating this high risk group.

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So essentially Abbott turned it down, GSK turned it down, but Abbott went up to the plate and took the risk to do the study, and that study is called REDUCE-IT.
Q Okay. I think you said Abbott. You meant Amarin; right?
A Amarin came -- stepped up to the plate; that is correct.
Q But this is referring to fibrates; right?
A Correct.
Q And the --
A Fibrates were the -- the study for fibrates was a Abbott study.
Q And the post hoc analysis you were referring to was looking at what the hypothesis would be for fibrates or for icosapent?
A For a -- a medicine that would lower triglyceride which fibrates lower triglyceride, but in the studies that had been done, they did not hone in or focus specifically on a hypertriglyceridemia population.
Q Okay. And then below that is TPP feedback.
Do you see that?

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A I don't know what TPP is.
Q Okay. So just going back to the fibrates and the post hoc analysis, is that because in a clinical study you have to define what you're looking for before the study occurs and looking at things afterwards can have bias?
MR. KENNEDY: Objection to form.
THE WITNESS: That's actually not true.
What -- what happened with the -- the study for the Abbott sponsored trial known as ACCORD, it was not -- Abbott provided the medication, but it was an N- -- it was an NHLBI study, National Heartland Blood Institute study.
And even though I was not involved in putting together the study, some of my colleagues were. And they asked NHLBI to focus in on a diabetic population with hypertriglyceridemia, and NHLBI said no. They turned them down.
Hence the intention was there to do the proper study. It didn't get done. But they were able to get in in the study a prespecified endpoint which looked at the hypertriglyceridemia, low HDL subgroup.
So when the study was over even though the results were negative -- no surprise to many

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of us -- they did have that prespecified endpoint of the hypertriglyceridemia, low HDL subgroup and within that group that was positive.
So, therefore, that led to Amarin stepping up to the plate to do the REDUCE-IT trial.
BY MR. CLEMENT:
Q But that positive finding, right, on this other endpoint, not the primary endpoint, but that other endpoint, that was based on patients taking fibrates?
A So the way the ACCORD study was devised -- is that diabetic patients with vascular disease were assigned to LDL-lowering therapy. So they all had to be on a statin and on top of that half the group was randomized to also receive the Abbott compound, the fibrate.
And the results here -- so the study was not powered sufficiently to -- to hone in on the hypertriglyceridemia, low HDL group, but the results -- certain -- trended in favor of benefit amongst those -- amongst that subgroup.
Q Taking the fibrate?
A Taking the combination.
Q Combination of fibrate and statin.

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A Right.
Q Right?
A It's what I would refer to as concomitant lipid-lowering therapy/concurrent lipid-lowering therapy --
Q Okay.
A -- combination.
Q Okay.
MR. KENNEDY: You okay? Do you need a break?
THE WITNESS: I'm fine.
MR. CLEMENT: Let's mark as Miller 8, a document with the Bates number -- I'm sorry. I should have been -- have been reading these -- 2739796.
(Miller Deposition Exhibit 8 was marked for identification and attached to the transcript.)
BY MR. CLEMENT:
Q Okay. Dr. Miller, I've put before you what looks like an invoice to me, Miller Exhibit 8.
Can you identify this for the record?
A Yes, it's Exhibit 8. It is to Paresh in regard to my consulting time for Amarin.

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Q And this is for the time period September through December 2010?
A That is correct.
REDACTED
Q And this is before serving on the steering committee for REDUCE-IT; is that correct?
A I believe at this time I was on the steering committee.
Q Even though on your CV it says 2012 and this is 2010 work, you think you started the steering committee work earlier?
A Yeah, because the -- I was approved by the American Heart Association and the NIH. If we go back to Exhibit 6, it looks like in March of 2010 --
Q Uh-huh.
A -- at which time I signed the consulting agreement, and then, I guess, we were in the process of finalizing the REDUCE-IT study. And, so, this would reflect that.
REDACTED

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REDACTED

MR. CLEMENT: Let's mark the next one. And this is going to be Miller 9, Bates number 2769565.

(Miller Deposition Exhibit 9 was marked for identification and attached to the transcript.)

BY MR. CLEMENT:

Q Dr. Miller, can you identify for the record what Miller Exhibit 9 is?

A This exhibit, again, is to Paresh regarding my consulting time between January and June of 2011.

REDACTED

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REDACTED

MR. CLEMENT: Okay. Let's mark the next one. Let's mark this Miller 10, a document with the Bates numbers 3121925 through 3121931.

(Miller Deposition Exhibit 10 was marked for identification and attached to the transcript.)

BY MR. CLEMENT:

Q Okay. Dr. Miller, have you ever seen this document before?

A I do not believe I have.

Q Okay. If you can just turn to the page with the Bates number 3121930.,

I guess, before turning there, this is a document that's talking about Amarin and the REDUCE-IT study in 2014.

Do you see that?

A I do.

REDACTED

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REDACTED

MR. CLEMENT: Let's mark Miller 11, a document with Bates number 1077327.

(Miller Deposition Exhibit 11 was marked for identification and attached to the transcript.)

BY MR. CLEMENT:

Q And, Dr. Miller, have you ever seen this document before?

A I see it now.

Q Okay. And this is another invoice that you sent to Amarin?

A Yes.

Q For the time period -- I guess, for two different time periods; right?

A That's correct.

Q One is for November 1 through

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December -- let's take it from the top.

The first one is for July through October 31, 2011; right?

A Correct.

REDACTED

Q And then the next period is November 1 through December 16, 2011.

A Right. All related to REDUCE-IT. That is correct.

REDACTED

Q -- again?

Have you ever, sir -- I guess, have you ever heard the term "KOL"?

A I've heard -- I've heard of it. I don't know what it means.

Q Key opinion leader.

A Oh, okay.

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Q Have you heard of that?
A Now I have, yes.
Q Okay. Have you ever served as a KOL for Amarin?
A Well, I guess not in the sense that I think of a key opinion leader. What pharmaceutical companies have done in the past and I don't know because things have changed over -- over the years, but key opinion leaders could vary between companies, and oftentimes a key opinion leader might be asked to do -- to do speaking engagements.
But in this particular case, this was related to serving on a committee for a clinical trial.
Q And forgive me if I misled you. I'm not speaking about that exhibit anymore.
I'm just asking have you ever served as a kay -- key opinion leader for Amarin in any context?
A I -- I'm not sure what that means, what the context you're referring to is.
Q Who do you currently interact -- so you're still working in some sort of consultancy -- consultancy capacity for Amarin;

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right?
A Right. I consider myself a member of the steering committee for the REDUCE-IT trial --
Q Okay.
A -- and advise them accordingly.
Q And who do you interact with at Amarin currently?
A A gentleman by the name of -- of Ralph Doyle.
Q Anyone else?
A There are others. I just don't remember all their names.
Q Okay. Do you remember any others, as you sit here today?
A No, but if you gave me a list of names, I could probably point them to you.
Q If I had a list, I -- we'll see. As we -- as we go through, if something comes to your mind, you know, just let me know, please.
MR. CLEMENT: Okay. Let's mark the next exhibit which will be Miller 12, a document with Bates range 1638777 through -- it's 877 and -- and through 8778, but there's also attach- -- an attachment.
(Miller Deposition Exhibit 12 was

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marked for identification and attached to the transcript.)
BY MR. CLEMENT:
Q Oh, I need to give it to you. Okay.
And, Dr. Miller, have you ever seen this document before?
A I do not believe so.
Q You're not listed on the emails; right?
A (Witness shakes head.)
Q Although it does talk -- it does note -- it says, Please note that Doctors Miller, Weintraub and Nissen are not involved in the trials. And it's giving a contact list for some KOLs.
A I see that.
Q Do you know who -- Paresh Soni, we have talked about; correct?
A Yes.
Q Do you know who this Martina Schwarzkopf is?
A I don't.
Q Do you know who David Schull is?
A I do not.
Q Or Elliott Fox?
A I do not.

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Q Or Russo Partners?
A I do not.
Q Okay. If you turn to the attachment, do you see you're listed there -- I guess this is their -- their list of key opinion leaders.
Do you see that?
A I see the list.
Q Okay. And your name is on that list?
A I see that.
Q And do you see a guy named John Kas- -- Kastelein?
A Yes.
Q Do you know who he is?
A Yes.
Q Okay. Would you consider him to be a person of ordinary skill in the art as you've set forth in your opinions in your declaration?
A Yes.
Q How about as an expert in the field?
A Yes.
MR. KENNEDY: Object.
BY MR. CLEMENT:
Q And what about Harold Bays. Do you know who that is?
A Yes.

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Q And would you consider him to be a person of ordinary skill in the art?
A Yes.
Q And an expert?
A Yes.
Q And what about James McKenney? Do you know who that is?
A Yes.
Q And would you consider that person to be a -- at least meet the standards of a person of ordinary skill in the art as you've defined it?
A I don't believe that Jim sees patients, so I'm not as sure about that.
Q Okay. What about Steven Nissen?
A Yes, I know him.
Q Okay. Would you consider him to at least be a person of ordinary skill in the art as you defined it in your declaration?
A Well, again, I don't know -- he's a cardiologist. I don't know how many patients he really sees with VHTG. It's important to -- to make a distinction because cardiologists, as a general rule, do not treat patients with VHTG.
There are exceptions. I'm one of the exceptions, but I have colleagues that are

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cardiologists that also see them. But by and large VHTG, because -- because of its relative rarity and the fact that it's not viewed as strikingly associated with cardiovascular disease, is generally not seen by cardiologist.
Q Okay. If you turn to your declaration which was Miller 2, I guess, and -- and look at your definition of -- I guess, which paragraph would you say contains your definition of a person of ordinary skill in the art.
A I believe we're looking at 15.
Q Okay. And where in 15 does it say that a person of ordinary skill in the art is required to have -- treat VHTG?
A So, one, I never used the word "required," and, secondly, Including severe hypertriglyceridemia is the way that this -- the two sentences are written, Including severe hypertriglyceridemia. And cardiologists, as a general rule, do not see those patients.
At the University of Maryland, for example, within my division, the echocardiographers, the interventionalists, the electrophysiologist refer -- they hear about a patient with very high triglycerides, they send

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them to me.
A general cardiologist does not typically see these patients.
Q Okay. So when you say, "including hypertriglyceridemia," that's a act- -- that's actually a requirement for your person of ordinary skill in the art. They actually -- they have to have that. It's in a -- it's a requirement when you say "including"?
A Well, again, to make them a more -- more reputable in field, you have to have experience in -- in treating whatever -- whatever your -- you're determining you're titled to.
Very high triglycerides are relatively uncommon. They're not -- it's not a bread-and-butter patient that a cardiologist sees that had -- that a cardiologist would simply place a person on a statin and say, you know, I treat patients with lipid disorders. That -- this is a little bit different.
Q Okay. Again, I'm just asking a question. I understand your position there.
Is it a requirement -- when you say, "including severe hypertriglyceridemia," is that a requirement for your person of ordinary skill in

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the art, that they are treating patients specifically with hypertriglyceridemia?
A Yes, I think they have to have some experience in this field, absolutely.
Q When you say "some experience," what does that mean?
A Seeing and treating patients with triglyceride levels of at least 500 on a regular basis, not once every five or ten years, but on a relatively frequent basis.
Q Okay. And going back to Exhibit 12 which was that list of KOLs. Do you still have that?
A Yes.
Q Thank you.
I think we left off -- the next one is Howard Weintraub?
A Yes.
Q And is he -- do you know who that is?
A Yes.
Q And is he someone who is at least a person of ordinary skill in the art?
A I believe he would be.
Q And an expert?
A I believe he would be.

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Q And, again, you don't know how this list was compiled; correct?
A That is correct.
MR. CLEMENT: Can we take a break.
MR. KENNEDY: Yeah, it's a good time for a break.
THE VIDEOGRAPHER: The time is 9:28 a.m. This completes tape number 1. We are going off the record.
(Recess -- 9:28 a.m.)
(After recess -- 9:49 a.m.)
(Jennifer Scarpati and Deepti Jain present.)
THE VIDEOGRAPHER: The time is 9:49 a.m. This begins media unit number 2.
Please proceed, Counsel.
BY MR. CLEMENT:
Q Dr. Miller, do you still have Exhibit 12 front of you?
A I do.
Q Just one further question. Bill Stirtan, do you know who that is? Did we talk about him before?
A We may have. I think I remember meeting him, but I don't know his whereabouts now.

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I don't believe he's with the company, but I just don't know.
Q Okay. Do you know if he's -- do you understand -- does he practice medicine or --
A I don't think so, but, again, I don't know.
Q Okay.
MR. CLEMENT: All right. Let's mark the next document, document with Bates number 2702696.
(Miller Deposition Exhibit 13 was marked for identification and attached to the transcript.)
BY MR. CLEMENT:
Q Dr. Miller, the court reporter has placed before you what's been marked as Miller Exhibit 13. Have you ever seen this document before?
A I -- I don't recall, but I'm seeing it now.
Q Well, it's a email from Steven Ketchum to you; correct?
A Yes.
Q And dated May 28th, 2013?
A That's what it says.

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Q Do you recall this document -- referring this document?
A I -- I really don't.
Q Can you take a second to just review it?
A (Witness reviews document.) Yes.
Q Okay. Did reading it refresh your recollection as to what it's about?
A Yes.
Q Okay. What -- what do you recall about it?
A Yeah. There was a -- there was a primary care conference with Pri-Med. So this is a conference that primary care physicians attend. It's continuing medical education. And a colleague and I gave a talk related to hyp- -- I spoke on hyp- -- just the general aspect of hypertriglyceridemia, and I believe he talked about treatment.
And I think that's probably where this came from.
Q And who was the other colleague?
A I don't recall now.
Q Okay. And was this part of your consultancyship with Amarin --

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A No.
Q -- that you appeared at this?
A No, so primary care -- I mean, Pri-Med conferences are CME conferences that are borne out from Harvard.
And, so, one of my colleagues, Peter Libby, over at Harvard does the cardiology and there are a number of colleagues from Harvard that are involved, so I get involved to speak at those.
Q Do you know who Steven Ketchum is who wrote this email to you?
A I do.
Q Okay. Who is Steven Ketchum?
A At the time at least of what was dated May of 2013, he was president of research and development and senior vice president of Amarin.
Q Okay. He sent you this little news wire, right, at the bottom?
A Correct.
Q And you were a member of the -- well, it says -- it says here that the firm says one lecture conducted by a member of Amarin's steering committee.
Are they referring to you there?
A I don't believe so.

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Q Do you have any idea who they were referring to?
A I believe it was probably the other speaker.
Q Okay. And you still -- you don't recall --
A No.
Q -- who that was?
Okay. And it says here that he said -- and, I guess, that's the other speaker?
A Correct. It was a male.
Q Male, okay.
However fish oil is one of many treatments that can lower triglycerides; right?
A That's what it says.
Q Okay. So there are other medications that can lower triglycerides in addition to fish oil; right?
A Correct.
Q And do you know what that was for -- that was for levels above 500; right?
A I -- I don't recall, so I'm -- like you, I am looking at this -- at this text to understand the context of it.
Q Okay. Do you recall having -- I mean,

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it says here that, you know, in the top, the email portion, it talks about Mike is -- he's writing to you, and he's saying he has some questions regarding the newswire piece and for you to feel free to call him.
Do you recall having a conversation with him about this?
A I -- I don't.
Q Okay. Have you ever talked to the patent inventors in this case?
A Well, I think as I -- as I said, I -- two of the patent inventors, Paresh Soni and Rene Braeckman, who approached me during the early part of the trial, but they both left the company, and I have not seen or spoken with them since.
Q Since -- do you remember -- give me a time frame?
A I'm guessing they left the company around 2013, maybe, '12.
Q Okay.
A Somewhere between '12 and '13.
Q And what about any of the other inventors on the patent?
A I don't believe I recognize them.
Q Do you know if any of them -- what -- I

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may have asked this before. Was Paresh Soni someone you considered a person of ordinary skill in the art?
A Well, again, I don't know the extent to which he is still in the field. This was 2012, so at that time he was -- at the very least he was familiar with the compound. And whether or not he had access to a clinician if he, himself, wasn't seeing those patients, is another issue.
Q So I guess I'm asking whether or not you can -- based on the knowledge as you sit here today, you can't tell me -- you don't know whether he was a person of ordinary skill in the art; is that correct?
A Well, I think based upon -- so if I may and go back to my declaration.
MR. KENNEDY: Yeah, you might have -- I think it's --
THE WITNESS: And I will go to that section of person of ordinary skill in the art.
And I said, It is my opinion that a POSA at the time of the invention would be a clinician with an M.D. or D.O. -- so he qualifies in that regard -- and at least two or three years experience of the diagnosis and diagnosis of

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treatment of lip- -- of treatment of lipid disorders including hypertriglyceridemia.
So that's just the part I'm just unclear of.
BY MR. CLEMENT:
Q All right. So sitting here today, I guess, in answer to my question, you don't -- you can't tell me whether or not he was a person of ordinary skill in the art; right?
A At that particular time, back -- back in 2011, that -- based on my -- that -- that -- again, this is my opinion, and it doesn't invalidate in any way the opinions offered in number 17; otherwise, it wouldn't change my opinions expressed in this declaration, provided that the POSA as defined by defendants and plaintiffs is or has access to a clinician. That's number 18.
Q Okay. And right. This -- and if we look at paragraph 17, right, plaintiffs in their preliminary validity contentions, you know, they don't make -- they don't talk about this severe hypertriglyceridemia; correct?
A They mention expertise in lipid metabolism.

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Q But they don't men- -- mention severe hypertriglyceridemia; correct?
A They don't say severe hypertriglyceridemia.
Q Okay.
A But they talk about expertise in lipid metabolism which might fall under the umbrella of a VHTG.
Q So it may or may not include it. I'm not saying it excludes it. It may or may not include it; right?
A Correct.
Q Okay. What's a D.O.?
A That's a -- a doctor of osteopathic medicine.
Q Okay. And you also say alternatively, right, a POSA that can be a nurse practitioner, physicians assistant with the criteria you spell out?
A Yes.
Q So they don't have to be a doctor?
A They don't have to -- they don't have to have a medical degree or an osteopathic degree, but they certainly need to have experience in treating patients with lipid blood disorders that

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include severe hypertriglyceridemia.
Q Can they prescribe medications, nurse practitioners?
A I think it depends on the state and the same holds true for physician assistants.
Q Again, turning back to the inventors, Rene Braeckman, sitting here today, can you tell me whether or not he meets your definition of a person of ordinary skill in the art?
A Again, based on this, I -- I don't know. He may.
Q All right.
A He may not. I don't know.
Q All right. Sitting here today, you don't know; correct?
A That is correct.
Q And you don't know any of the other inventors, so you can't opine on whether or not they would meet that --
A That --
Q -- criteria?
A -- is correct.
Q Okay. Now, you're affiliated with the University of Maryland, Baltimore; is that right?
A Yes.

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Q And what's your position there?
A I am a professor of cardiovascular medicine, epidemiology and public health at the school of medicine.
Q Can you define "epidemiology"?
A Epidemiology is the study of -- of populations and assessing various entities which might be disease or characteristics at least from a cardiovascular standpoint.
Q When you say "populations," you're talking a number of people; right?
A Correct.
Q And in your practice, do you also see patients?
A Yes.
Q Okay. And are they only patients who have severe hypertriglyceridemia?
A No.
Q How -- I guess, what percentage of your patients have severe hypertriglyceridemia?
A So let's call it just VHTG.
Q Okay.
A It will make -- it will make -- it will make it much easier --
Q Thank you.

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A -- defined as a triglyceride of at least 500 milligrams per deciliter.
In the U.S. population that -- the prevalence is approximately one in 100 individuals. In my practice, I probably see somewhere -- prior to my declaration, about 20 a month. So 20 a month would be a relatively small percentage of the patients that I see in general.
Q Are you affiliated with any other medical institutions?
A No.
Q And, I guess, what percentage of your time, a ballpark, in any given year do you spend seeing patients?
A I believe I have in my declaration approximately two-thirds.
Q And do you prescribe medications?
A I do.
Q Do you describe -- prescribe blood thinners?
A I do.
Q To patients with over -- who are VHTG?
A If they need it.
Q So you do have patients who are over -- who are VHTG and on blood thinners?

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A Yes.
Q Do you prescribe Lovaza?
A Yes.
Q Vascepa?
A It's Vascepa, yes.
Q Vascepa, okay. Thank you. I've been pronouncing it wrong for a few years now.
And that's an Amarin product; right?
A Yes.
Q Is that their only product?
A I don't know.
Q Okay. Do you prescribe statins?
A Yes.
Q Ezetimibe, if I pronounce that correctly?
A Ezetimibe or Zetia.
Q Ezetimibe or Zetia, yes.
A Yeah.
Q Fenofibrates?
A Yes.
Q Do you prescribe fenofibrates to patients who are VHTG?
A Yes.
Q What about niacin?
A I don't use a whole lot of niacin any

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more.
Q But you still do -- you still do prescribe it?
A There might be a patient who has been on the medication for many years that does not want to go off of it, so -- but I do not -- it would be uncommon for me to initiate a new script for niacin.
Q Okay. And are you familiar with package inserts?
A Yes.
Q Also -- do you also refer to them as labels sometimes, or do you prefer package inserts?
A It doesn't matter.
Q Okay. And do pharmaceutical companies in coordination with FDA often get revisions to their package inserts?
MR. KENNEDY: Objection to form.
Go -- go ahead.
THE WITNESS: They may.
BY MR. CLEMENT:
Q So different versions can include different information, right, of a package insert?
A Yes.

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Q And they usually have a date on them with the last revision?
A I'll accept that.
Q Okay. And that would be the date of the package insert?
A I don't know, but I'll accept that.
Q Okay. All right. Turning back to the person of ordinary skill in the art, I think you stated in your declaration -- and feel free to look at it -- but that we -- you have in there a 2009 date for the person of ordinary skill in the art, I think, if you look at paragraph 14.
A Yes.
Q And do you know how you came up with that date?
A Yeah, I believe that was when the earliest patent application was filed.
Q Give me one second here.
MR. CLEMENT: Sorry about that. Let's mark as Miller Exhibit 14 a copy of U.S. patent number 8,293,728.
(Miller Deposition Exhibit 14 was marked for identification and attached to the transcript.)
BY MR. CLEMENT:

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Q Dr. Miller, the court reporter has marked -- put before you as Miller Exhibit 14 the '728 patent.
And you've reviewed that; right?
A Yes.
Q And, I guess, do you know where on this patent it shows where the filing dates were for the -- by which you determine the 2009 date for a person of ordinary skill in the art?
A Well, I'm not sure this patent refers to the 2009 -- there -- there was a '727 and other patents that preceded it.
Q Okay. But if you look at -- if you look at the front page of this document, okay?
A Yes.
Q You see, like, in the left hand column there's numbers in parentheticals?
A I see those numbers.
Q Okay. And there's one that says 60?
A Yes.
Q Okay. Do you see where it has provisional applications based on a 2009 date?
A Yes.
Q Is that where you got it from?
A Provisional. I believe so.

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Q So the earliest -- if we want to get to the actual date, the earliest date that this application has for its priority, at least on the front page of this document, is February 10, 2009; right?
A That's what it says.
Q Okay. And I think we've already agreed that paragraph 15 of your opening declaration, that's where your definition of the person of ordinary skill in the art is?
A Yes.
Q Okay. How many people in the United States do you think meet your definition of the person of ordinary skill in the art?
A I would say -- I don't have -- I can't give you a number.
Q How about a -- you're in the Baltimore area? Is that where your practice is?
A (Witness nods head.)
Q How many in the Baltimore area do you think meet your definition of the person of ordinary skill in the art?
A Oh, probably about one to two dozen.
Q And do you know what the NLA is?
A I do.

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Q And what is the NLA?
A NLA is the National Lipid Association which is at -- the flagship organization for those interested in lipid disorders and treating lipid disorders.
Q What about in the D.C. area? Do you have an estimate of how many doctors you think in the D.C. area or people in the D.C. area would be -- meet your definition of a person of ordinary skill in the art?
A I would have to look to see. I'm not as familiar with --
Q Okay.
A -- the -- who I might view as experts in this area.
Q But how many cardiologists do you think there are in the Baltimore area?
A Myself and at least three at Johns Hopkins.
Q Are the only cardiologists?
A That are interested in lipids.
Q Okay. What about --
A But -- that treat lipid disorders -- not treating a patient that comes in -- that they put on a statin for an elevated LDL that they call a lipid disorder when it's not.
Q Well, let me ask you this question. Would you turn to paragraph 17 of your declaration which has plaintiff's definition and their validity -- preliminary validity contentions.
A Uh-huh.
Q How many people have an advanced degree and advanced training expertise in lipid metabolism or cardiology or have experience in the diagnosis, evaluation and treatment of blood disorders? How many of those do you think are in the Baltimore area?
A Probably about a dozen.
Q You realize this doesn't limit it to people who treat VHTG?
A So that -- that -- my interpretation here would include the treatment of VHTG -- would include --
Q Would include but wouldn't be limited to that; right?
A No.
Q So if we don't limit it to people who treat VHTG, you think there's only a dozen people in the Baltimore area that meet that definition?
A Probably, give or take.

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Q Have you ever heard of the term "dyslipidemia"?
A Yes.
Q What does that mean?
A Abnormal level of lipids and/or lipoproteins.
Q So is that only people who have VHTG?
A No.
Q What about the term "monotherapy"? Have you ever heard that -- heard that term before?
A MT, yes.
Q And what does that mean?
A Monotherapy, to me, is using a single drug.
Q What about the term "adjunct" or "adjunctive therapy"?
A Very general term.
Q Okay. What does that term mean?
A Adding to -- adding therapy to whatever is existing already.
Q So you have -- if you have adjunctive therapy, the therapies are overlapping?
A It could be.
Q They're happening at the same time?

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A Patients can take -- can incorporate them together.
Q They're concomitant?
A Well, concomitant, the way it's defined in this specific patent refers to lipid-lowering therapy, so that's outside the definition that you're referring to. But within the scope of this patent, concomitant refers to lipid-lowering medication -- medications.
Q Okay. But at -- at -- what I'm asking you is, adjunctive therapy, is that similar to concurrent therapy?
MR. KENNEDY: Objection to form.
THE WITNESS: It may or may not be.
BY MR. CLEMENT:
Q Is it similar to concomitant therapy?
MR. KENNEDY: Same objection.
THE WITNESS: It may or may not be.
BY MR. CLEMENT:
Q How -- how might it not be?
A Well, so the way I view concomitant therapy, for example, in the sense of taking a combination of lipid-lowering medications would be that a patient has -- is -- comes in, is found to have hyperlipidemia and is placed on a statin.

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LDL is still high so that ezetimibe is added to continue LDL reduction.
So that is -- I would view that as concomitant lipid-lowering therapy.
Q Would you view that as adjunctive therapy?
A I don't think of it like that. I just don't.
Q But adjunctive therapy is still overlap -- therapies that overlap?
A Therapies that overlap, but in the field we -- I don't think of it like that.
Q Do you own -- have any -- are you an inventor on any patents?
A Not as of 2009.
Q How about to- -- as you sit here today?
A Not today.
Q Are you an inventor on a patent application?
A Not today.
Q Not today, okay.
It's like -- what I'm trying to get at is, you know, your prior experience with patents, let's say, in 2009 -- well, let's -- let's say -- well, strike that.

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I guess, what is your understanding of what claim construction is?
A If I may refer back to my declaration --
Q Uh-huh.
A -- where I define "claim construction principles," and that's on page 7. And that is a claim term that is given its plain and ordinary meaning as it would be understood by a person of the ordinary skill in the art within the context of patent claims, specification, prosecution history.
Q Anything else?
A It could be extrinsic evidence as well.
Q Okay. Have you ever heard of the doctrine of claim differentiation?
A No.
Q And you cite to the prosecution history in support of what a claim construction could be; right?
A Yes.
Q What is your understanding of what a prosecution history is?
A Well, prosecution history is basically all of the elements -- the history behind the --

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the patent submission.
Q And have you ever been involved in a patent prosecution proceeding?
A No.
Q And before this case, have you ever looked at a prosecution history?
A I don't believe so.
Q Now, in paragraph 20 of your report, you talk about the patentee can expressly define the claim term.
Do you see that?
A Yes.
Q Did you find any express definitions on the claim terms you opined on?
A If I may go through.
Q Sure. Take a minute.
A (Witness reviews document.)
So if we go to . . .
(Witness continues reviewing document.)
Yes, I think throughout where there's discussion as to the use of this medication to lower triglycerides without raising LDL and/or to lower ApoB which is certainly within the -- something that I've spoken about.
Q Okay. I'm asking do you have any

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instances of where the patent specification gave you an express -- an express definition of a claim term.

I guess -- I'm confused by your answer. Maybe you can help make --

A I guess --

MR. KENNEDY: Objection to form.

THE WITNESS: I guess, I'm confused by your question.

BY MR. CLEMENT:

Q You say here in paragraph 20, right, I also -- I also understand that the patentee may expressly define the claim term in the patent specification, and if the claim is defined, then that definition will govern.

So I guess I'm asking you was there a place in the patent that you looked to -- the patent specification that you looked to that gave an express definition of a claim term. And you said, okay, that's what the specification said; that's how it's defined?

A Yeah, I think for -- in the instance of administering, for example, that's one example in the patent specification -- I mean, in the prosecution history.

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Q I'm asking the patent specification.

A I believe there are in the patent application and patent specification. There are instances where I've discussed that, so I'm going to have to go through these. So if you give me a moment here.

If we go to page 24, under number 55, in discussing lipid-altering therapy, it is clear from the specification that concurrent and concomitant lipid-altering therapy concur solely to medications. For example, the specification describes that in one embodiment the subject being treated in accordance with methods of the invention is not otherwise on lipid-lowering therapy. For example, statin, fibrate, niacin and/or ezetimibe therapy.

Q And you consider that an express definition; is that your testimony?

MR. KENNEDY: Objection to form.

THE WITNESS: Well, I'm not an attorney, but based on what is written, I go into a claim term within the patent specification, and that claim term here relates to concurrent lipid-altering therapy to the extent that that is discussed in the specification.

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BY MR. CLEMENT:

Q And that's -- you have the '728 patent, column -- you rely on the columns 12, lines 43 to 46 for that?

A (Witness reviews document.) Yes.

Q And you consider that as the declarant of your deposition, you consider that to be -- I just want to get your testimony correct.

You -- as the declarant of this declaration, you consider that to be an express definition that the patent was given; correct?

MR. KENNEDY: Objection to form.

THE WITNESS: I think this is one of a number of examples as it relates specifically to the specification.

BY MR. CLEMENT:

Q That's not what I'm asking.

I'm asking as the declarant, the person whose opinions are contained in your declaration, you consider what is at column 12, lines 43 to 46, to be an express definition; is that correct?

MR. KENNEDY: Objection to form; asked and answered.

THE WITNESS: Yeah, I -- as I've already said, I'm not an attorney and based on the

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information as presented with -- with regard to the specification on concurrent lipid-altering therapy and concomitant lipid-altering therapy in one embodiment within the '728 claim -- the '728 patent, that that information suggests that.

BY MR. CLEMENT:

Q Well, that's one embodiment; right. An embodiment is an example. It's not a definition; right?

MR. KENNEDY: Objection to form.

THE WITNESS: Correct.

BY MR. CLEMENT:

Q Okay. So is that an expressed definition -- sitting here today -- you're the one who wrote the declaration and offered opinions and you talked about expressed definitions in your declaration. I'm just asking you is that -- under your understanding, not an attorney's -- under your understanding as a declarant offering opinions in this case if what's at columns 12, lines 43 to 46, is an expressed definition of the term "concurrent or concomitant lipid-altering therapy"?

MR. KENNEDY: Same objection.

THE WITNESS: Yeah, and I think you

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need to review not only the term and the specification, but you also need to review the -- and incorporate prosecution history and extrinsic evidence.

BY MR. CLEMENT:

Q If it was an expressed definition, would you need to consult the prosecution history as well?

MR. KENNEDY: Objection to form.

THE WITNESS: And, again, I'm not an attorney, so I'm -- I'm not as -- as --

BY MR. CLEMENT:

Q When you say --

A -- as well as an expert in this specific --

Q In paragraph 20 you say -- I understand, right, that the patentee may expressly define the claim term in the patent specification, and if the term is defined, then that definition will govern.

So there will be no need to go to the prosecution history, right, if there was an express definition?

A Well, but the next sentence says, I understand that an applicant may also

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intentionally disavow or limit the scope and claim of the statements made to the patent office during prosecution which is prosecution history.

Q Understood.

But, again, if the term is defined and that definition -- are you telling me that what's at column 12, lines 43 to 46 -- is that or is that not an express definition of the claim term "concurrent or concomitant lipid-altering therapy"?

MR. KENNEDY: Objection to form.

THE WITNESS: Yeah, I'm not sure. In and of itself, it's an expressed term, but it is certainly one example of -- as noted in the specification for which concomitant/concurrent --

BY MR. CLEMENT:

Q Okay.

A -- therapies --

Q So you're not sure. That's fine. That's a fair answer.

I'm asking you are there any instances in the patent specification where you think the patentee expressly defined a claim term in the patent specification that you have relied on in your declaration?

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MR. KENNEDY: Objection to form.

THE WITNESS: Yes, I -- I have not relied uniquely on the patent specification. I've considered it as I've considered all of the intrinsic evidence and to some extent extrinsic evidence. So I've looked at all the information presented to me.

BY MR. CLEMENT:

Q Understood.

I'm asking a question. You know, it's -- to me, it's a yes/no question, but -- are there any instances where you thought that in the specification there was an express definition of a patent claim term that you opined on?

MR. KENNEDY: Objection to form.

THE WITNESS: Yeah, I'm not sure that I did.

BY MR. CLEMENT:

Q Okay. Now, the next part of your sentence -- your statement in paragraph 20 talks about the prosecution history, right, where there can be an intentional disavowal or a limiting of the scope of the claim; right?

A Yes.

Q Did you find instances of either of

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those, an intentional disavowal -- I guess, strike that. Let's take it back a step.

What do you mean by "intentionally disavow"?

A Oh, boy. Go against, disprove.

Q Okay. But intentionally disavow or limit the scope of a claim -- so I guess take it in context.

A Yeah.

Q Are you still good with go against or disprove?

A Yeah, that's fine.

Q Okay. What about limit? Same?

A Yeah.

Q And are there any instances of an intentional disavowment or limitation of the scope of a claim in a statement made to the patent -- patent office during prosecution that you relied on in your declaration?

A I don't believe so.

Q Now in paragraph 21 you discuss the use of extrinsic evidence; right?

A That is correct.

Q What is extrinsic evidence?

A Well, it is information that may have

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not been part of the original submission related to the patent prosecution history specification.
Q Do you know what intrinsic evidence is with regard to claim construction proceeding?
A Intrinsic evidence incorporates.
Q The intrinsic?
A Extrinsic evidence is -- is outside of the intrinsic evidence.
Q Okay. And what is the intrinsic evidence?
A And the intrinsic evidence includes specification, prosecution history.
Q And the claims?
A And the claims.
Q Okay. And extrinsic evidence is anything other than the intrinsic evidence; right?
A Yes.
Q Okay. Are you aware of any limitations on the use of extrinsic evidence in claim construction?
MR. KENNEDY: Objection to form.
THE WITNESS: Again, I'm not an attorney, and I don't know.
BY MR. CLEMENT:
Q Yeah, I'm not asking as an attorney.

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I'm asking as a declarant.
You relied on some extrinsic evidence; right?
A I did.
Q Okay. I'm just wondering -- are you aware of any limitations on the use of extrinsic evidence in claim construction?
A Well --
MR. KENNEDY: Objection to form.
THE WITNESS: Only insofar as if the extrinsic evidence comes out after the patent application has been submitted.
BY MR. CLEMENT:
Q So if it postdates that 2009 date --
A Yes.
Q -- it shouldn't be considered; right?
A Well, the 2009 -- I think we have patents that extend into the 2012, 2013 time frame. I mean, there are a number of different patents.
Q Right. But they all rely on a 2009 filing date; right?
A Right. Correct. Correct.
Q So anything after that 2009 date should not be considered extrinsic evidence; right?

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A Yes.
Q Do you know if extrinsic evidence is given lesser or greater import than intrinsic evidence?
MR. KENNEDY: Objection to form.
THE WITNESS: I would say it's given less evidence.
BY MR. CLEMENT:
Q When did you first learn of using fish oil in treating lipid blood disorders?
A Well, my interest in fish oil dates back to 1987. I was a Fellow at Johns Hopkins and -- actually it dates earlier than that. To get the position at Hopkins I had to write a grant.
So it was an NIH grant that looked at the -- how different fatty acids were taken up, and it was my idea for the grant -- submitted the grant. It was funded. We did the study. And it was the first demonstration of looking at different oils taken up by cellular -- into the cells of a fibroblast.
And I looked at palmitate, oleate. So palmitate is a saturated fat. Oleate is an example of a monounsaturated fat. And I also

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looked at EPA. Back in those days EPA was quite expensive. I used half my grant to buy EPA, but there had been no data in the field at that time.
And showed -- it was one of those ah-ha moments when I looked at the simulation counter and found that when you use EPA compared to palmitate or oleate, it was directly taken up into cellular phospholipids with minimal amount taken up into triacylglycerol.
And, so, that sparked interest in -- in understanding this field better. So this was back -- this was circa -- circa 1987 when I did those experiments.
So that was my first entry into the field and subsequent to that the studies came out to show that actually a -- triglycerides are reduced in patients that had degrees of hypertriglyceridemia, and, so, there are studies done here in the States as well as outside the U.S. that have demonstrated in hypertriglyceridemic states -- omega-3 was preference. I mean, we actually identified the mechanism by which we believe -- to be taken up at the cell level.
And studies have demonstrated time and

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again that omega-3 preps, EPA, DHA as well, can reduce -- can lower triglycerides pretty significantly.

Q Now, EPA, that's icosapent?

A Correct.

Q And in that grant that you were talking about that you did back in circa 1987, were you getting purified EPA?

A Got purified EPA.

Q Do you recall how pure?

A It was -- as far as I knew, it was over 95 percent pure.

Q Now, when was the first time you learned of using purified EPA to treat high or VHTG?

MR. KENNEDY: Objection to form.

THE WITNESS: Well, in -- in -- in the United States, we -- I don't recall that we had a purified EPA product that was available until Vascepa came out.

BY MR. CLEMENT:

Q What about not in the United States?

A Yeah. There were preparations that were not used in the United States.

Q What preparation were those?

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A There was a -- a preparation that was also EPA based.

Q Can you tell me what it was?

A Well, it was Japanese. A preparation known as Epadel was marketed.

Q That was to treat VHTG?

MR. KENNEDY: Objection to form; outside the scope of --

THE WITNESS: Yeah, it --

MR. KENNEDY: -- the --

THE WITNESS: -- was --

MR. KENNEDY: -- declarations.

THE WITNESS: As far as I know, it was not used to treat VHTG. The first time that my understanding for the use of purified EPA to treat VHTG was here in the States. The other -- there was another preparation, but it was not -- as far as I know, it was not tested for VHTG outside the United States.

BY MR. CLEMENT:

Q What other preparation are you referring to?

A The --

MR. KENNEDY: Objection to form.

THE WITNESS: The Epadel compound.

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BY MR. CLEMENT:

Q The Epadel, okay.

Just so far as you know, it wasn't used to treat VHTG?

A Yeah, I'm not -- I don't recall publications on VHTG.

Q Okay. But you do recall hearing about Epadel before 2009?

A Yes.

Q To try high triglycerides at least?

A No, it was not used to treat high triglycerides.

Q What was it used to treat?

A It was -- it was used in a clinical trial called JELIS, and there was an outcome study. And, in fact, I believe they excluded patients that had VHTG. So it was specifically looking at whether or not the addition of this compound to standard of care in a Japanese population would lower their risk of cardiovascular events. It was a non-VHTG population.

Q Okay. Even though it was a non-VHTG population, was it used to treat lowering triglycerides in this non-VHTG population?

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MR. KENNEDY: Objection to form.

THE WITNESS: No, it was not.

BY MR. CLEMENT:

Q What was it used for?

A It was used to determine whether it had cardioprotective effects. And, in fact, in the original study, the amount of triglyceride reduction was -- was about 5 percent. It was not -- nowhere near as robust as we see with the studies that have -- for example, the MARINE study that had come out in VHTG patients.

Q So in the JELIS study or the use of Epadel, they weren't measuring reductions in triglycerides in the patient population that was studied; correct?

A It was not -- it was not a primary measurement. They did a whole lot of measurements in that and triglycerides like LDL, like HDL, like inflammatory parameters, it was just one of the number of markers that was looked at. But it was -- the study was not designed to hone in -- to look at triglyceride reduction.

Q Understood.

But I guess my question is triglycerides was one of the markers that they did

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measure in that JELIS study?
MR. KENNEDY: Objection to form.
THE WITNESS: It was one of a number of many, many markers, so I would discount the relevancy of triglyceride in this study.
BY MR. CLEMENT:
Q Okay. Now, in paragraph 22 of your declaration, you talk about how -- or determine what the patents were related to; right?
Do you see that?
A I do.
Q How did you determine what to put in that statement?
A Well, that -- that was -- that was determined based on the dose used in the MARINE trial to cause reductions in triglyceride as well as not to raise levels of LDL, also lowered levels of ApoB.
Q It says nothing about LDL or ApoB in paragraph 22; right? I'm not missing something?
A That's correct, not in that particular paragraph.
Q Did you look at the claims of the patents-in-suit because you -- I mean -- strike that.

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Did you look at the claims of the patents-in-suit in figuring out what to say in paragraph 22?
MR. KENNEDY: Objection to form.
THE WITNESS: I looked at the patents-in-suit, but the patents really relate to the use of this compound ethyl icosapent at a dose of 4 grams a day in patients with very high triglycerides.
BY MR. CLEMENT:
Q So you didn't look at the claims in coming to this statement; is that your testimony?
MR. KENNEDY: Objection to form.
THE WITNESS: I looked at the claims for this study.
BY MR. CLEMENT:
Q You looked at the claims of the patent --
A Of the patents, correct.
Q -- in coming to this statement in paragraph 22?
A Well, I think this is just one paragraph. As we go on, we talk more about some of the other elements. But as far as technical background, the idea of treating very high

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triglyceride levels with this particular therapy was really -- the -- the first demonstration of effectiveness without causing undue related issues.
Now, I do talk about the effects on LDL and ApoB a little bit later on --
Q Right.
A -- but, no, for this particular paragraph, that's the way this paragraph was written.
Q Okay. And did it come from the claims of the patent? And I agree you have other stuff in here, but I'm just asking whether or not this paragraph -- did it come from the claims?
A I'd have to go look at all the claims to see if I took word for word out of this, but I think this is just a general idea of -- of the reason for considering this particular medication.
Q Did the claims play a role in forming your opinion in paragraph 22?
MR. KENNEDY: Objection to form.
THE WITNESS: Well, the claims talk about some elements noted in paragraph 22.
BY MR. CLEMENT:
Q Okay. Which elements?

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A Very high -- very high triglyceride levels. Now, the claims might say 500 to 1500. They generally talk about the dose of 4 grams, and they -- and some of the claims talk about some of the -- well, some of those effects are also -- are -- are discussed in -- in the prosecution history. Some of them -- so if this is kind of a statement related to --
Q But some of them are talked -- right, the cause-specific effects on lipid parameters in patients; right? Some of those are talked about in the claims; right?
A If I may refer to '728 --
Q Sure.
A So if we look at '728 in claim 1, it does say it's a method of reducing triglycerides in a VHTG patient and goes on to say to effect a reduction in triglycerides without increasing LDL.
Q So that's part of -- so part of paragraph -- so just correct me if I'm wrong. You did consider the claims in coming to your statement in paragraph 22 of your declaration; right?
A Yes.
Q And here you say, To cause specific

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effects on the lipid parameters in patients; right? Is that correct?
A To cause specific effects.
Well, we know now; it was not appreciated back then. So when the study was designed, the finding of a -- a rise or lack of a rise in LDL was unexpected finding.
Q Understood.
A But at the time -- when I wrote this, it was --
Q And you said it -- it was to cause the specific effects on lipid parameters in patients; right?
A Correct.
Q In paragraph 22?
A Correct.
Q You did not say intend to cause; correct?
MR. KENNEDY: Objection to form.
BY MR. CLEMENT:
Q Correct?
A Correct.
Q Okay. And what is your definition of "patients"?
A Well, as it relates to the -- to the

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patents in this particular case, patients are a class of -- a class of individuals who have very high triglyceride defined as a --
Q Okay.
A -- triglyceride of at least 500.
Q Very good. That -- that's fine.
I guess, what is -- a patient in general -- I guess, can you give me your general definition of "patient"?
MR. KENNEDY: Objection to form.
THE WITNESS: Yes. So this is -- you're referring to something outside --
BY MR. CLEMENT:
Q Outside the patent.
A -- outside the patent.
A patient is someone who has various -- one or more medical issues that they're coming in for evaluation.
Q And would you agree a individual can be a patient or may not be a patient; right?
A I would agree.
Q Okay. And when we go back -- going back to the patent now, and we're talking about the definition of treating -- I'm sorry.
We're talking about how you state in

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paragraph 22 that there's a method of treating; right? What is your definition of "treating"?
A Well, in this particular case it's using the medication ethyl icosapent
Q To relieve the symptoms or to relieve the VHTG?
A To lower triglycerides and perhaps other effects.
Q Now, if you look at the '728 patent for me at column 2, line 33 to 40.
Do you see that section?
A I do.
Q If you'll just read that to yourself and let -- I guess, my question while you're reading that is if that's basically your understanding of what treatment means with regard to these patents.
A (Witness reviews document.)
Yes, I'll agree with that.
Q Okay. And you also discuss ApoB in your report?
A I do.
Q Okay. ApoB is short for what -- apolipoprotein B?
A Apolipoprotein B.

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Q Okay. I wasn't sure if I was pronouncing that one right either.
A Yeah.
Q We'll just use ApoB.
A Sure.
Q What is ApoB?
A Well, it is a -- it is a protein that resides on the surface of lipoprotein particles. There are lot of different ApoBs and lots of different Apo- lipoproteins. And they may be taken up by specific receptors or send signals to allow that particle to be metabolized and so forth.
Q And is it used as a measure of the number of VLDL, IDL, and LDL particles in the blood?
A Yes, it's -- it is often used as a surrogate for the so-called non-HDL so all lipoproteins but HDL.
Q And who uses it as such a measure?
A Well, oftentimes it's -- it's used in clinical trials.
Q How about in general practice?
A Not commonly.
Q When you see patients with VHTG, do you

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order -- when you take blood and -- do you order an ApoB --

A Not --

Q -- level?

A Not usually. I might on some occasions, but not all the time.

Q Let's mark the next exhibit -- we're up to --

THE COURT REPORTER: Fifteen.

MR. CLEMENT: -- 15 -- a document with a Bates range 289915 through 290194.

(Miller Deposition Exhibit 15 was marked for identification and attached to the transcript.)

BY MR. CLEMENT:

Q And, Dr. Miller, have you ever seen this document before?

A I have.

Q Can you identify it for the record?

A This is the third report of the national cholesterol education program expert panel on detection, evaluation and treatment of high blood cholesterol in adults, also known as the adult treatment panel III, final report.

Q And this is a -- this was an exhibit to your opening declaration; right?

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A I believe --

Q If you can look at paragraph 13 of your report, that might help you.

A I think part of it was, but . . .

Q Not paragraph 13. I'm sorry. Page 13.

A Yes.

Q Okay. And in -- on page 13, you -- you define that report, what we've marked as Miller 15, as the operative report discussing lipid parameters and standard of care as of 2009; right?

A Yes.

Q Has there been a subsequent report? Is there a --

A Yes, in 2013.

Q Okay.

A But it's not part of the National Cholesterol Education Program. It was reformatted under the auspices of the American Heart Association and the American college of cardiology.

Q Okay. Now, if you look on the first page of this report -- actually on every page at the very bottom there's a downloaded notation.

Do you see at the very bottom?

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A Uh-huh. I do.

Q Downloaded on November 13, 2014.

Do you see that?

A I do.

Q Did you download it on November 13, 2014?

A I don't recall.

Q Did this document come from counsel for preparation of your report?

A It could have. I've -- certainly have downloaded the report in the past. I just don't know if that was the day I did it.

Q So if you turn to page 289557 --

MR. KENNEDY: I'm sorry. Did you say 557?

MR. CLEMENT: 289957.

MR. KENNEDY: 957.

MR. CLEMENT: I'm sorry.

MR. KENNEDY: Thank you.

MR. CLEMENT: I misspoke. Thank you.

BY MR. CLEMENT:

Q And that's a discussion of ApoB?

A Yes.

Q And it says there that ApoB is a potential marker for all atherogenic lipoproteins;

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right?

A Yes.

Q What are atherogenic lipoproteins?

A All lipoproteins besides HDL.

Q Okay. And this is saying it's a potential marker for those; right?

A Yes.

Q And that's what it was in 2009; right?

A Yes.

Q And then it says a couple of sentences later that the body of evidence in favor of apolipoprotein B has not been developed sufficiently to justify replacing LDL cholesterol; right?

A Yes.

Q Do you agree with that statement?

A I -- I think with -- in -- in 2009 that is probably the way it was viewed.

Q I think consistent with your practice, what you just told me about your practice and that you don't typically order ApoB tests on your patients, the final sentence on that paragraph that carries over to the next column says that the non-HDL cholesterol measure is readily available in clinical practice whereas standardized ApoB

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measures are not widely available and in any case would add expense beyond routine lipoprotein analysis.

Would you agree with that statement as of 2009 time period?

A As -- as the -- yes, as -- as the way it was written, I would.

Q Okay. We can put that away right now.

I think in your report you also talk about chylomicrons.

A Yes.

Q What are chylomicrons?

A Chylomicrons are basically a -- fat particles that occur after diet ingestion of fat -- dietary ingestion of fat.

Q And, I guess, you know, one -- if you turn to paragraph 31 of your declaration, and maybe it's just the way I'm reading it but just trying to get some clarity on something.

The last sentence of that paragraph says, Lipid levels are -- lipid levels are typically measured in the fasting state in order to eliminate chylomicrons which are highly variable in the circulation based on dietary intake of fat.

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Do you see that?

A No. What page are you talking to?

Q Are you on paragraph 31?

A Oh, paragraph 31.

Q Sorry.

And I'm just looking at the last sentence.

My question is how does measuring lipid levels in the fasting state eliminate chylomicrons, or am I misreading the point you're making?

A So after you have a meal that contains dietary fat, depending on how much fat you consume, that fat gets processed into chylomicrons which enter into the circulation shortly after you have a fat meal, peaks in the circulation somewhere in terms of triglyceride levels -- peaks somewhere at about four hours and then over time generally gets metabolized out. That's why you tend to have a higher triglyceride level after you eat dietary fat, and that is related to chylomicron uptake.

But if you look at the fasting state, then you're presumably ridden of chylomicrons. And you're honing into the other primary

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triglyceride-rich particle or microprotein which is VLDL.

Q So you're just saying here that if you measure lipid levels in the fasting state, you're likely not to have chylomicrons?

A Well, generally, yes.

Q And that's what you're trying to convey here?

A Yes.

Q Okay. All right. Are elevated -- in 2009, were elevated levels of triglycerides associated with atherosclerosis?

MR. KENNEDY: Object.

THE WITNESS: To a point.

BY MR. CLEMENT:

Q What do you mean "to a point"?

A To a point. Elevated levels are viewed -- elevated levels of triglycerides tend to be viewed as associated with atherosclerosis until you get to very high levels.

So there is a distinction that the writers of ATP III going back to the 1980s -- well known for a person of ordinary skill in the art who treats patients with lipid disorders; that as triglycerides get into the very high range,

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they're susceptibility to atherosclerosis is reduced, whereas the -- the likelihood toward or the risk of pancreatitis goes up.

Q So, I guess, what levels -- when you say "very high range," as the triglycerides get into the very high range, what range are you referring to there?

A About 500.

Q About 500?

A About 500 starts to set the stage.

Q So about 500 triglycerides are not associated with atherosclerosis?

MR. KENNEDY: Object to the form.

THE WITNESS: I didn't say that.

BY MR. CLEMENT:

Q Okay. Then maybe I misunderstood. That's why I'm asking the question.

A Above 500, the level is still up. But as you continue to go up there's what we refer to as an inverted U-shape distribution as it relates to triglycerides in cardiovascular disease.

And anybody who treats patients with lipid disorders and treats high triglycerides would appreciate that at very high triglyceride levels, somewhere probably about 800 to a

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thousand -- we say 500, but clearly that -- that risk is still increased -- but it starts to go down as we move up closer to 800 to a thousand.

Q So what risk goes -- starts to go down as you get to 800 --

A Well, cardiovascular.

Q Cardiovascular?

A Cardiovas- -- some -- it peaks somewhere in the 2- to 600 range and then starts to go down. It's not a continuum risk as LDL level is. It's different.

Q So even below 500, triglycerides are associated with atherosclerosis?

MR. KENNEDY: Objection.

THE WITNESS: The risk of atherosclerosis probably starts to go up somewhere in the hundreds.

BY MR. CLEMENT:

Q And is it something doctors want to treat if they get a patient who has a level of 350 triglyceride? Is that something they want to treat to help prevent atherosclerosis in the 2009 time frame?

MR. KENNEDY: Objection to form.

THE WITNESS: And -- and this is where

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we've begged to have a clinical trial to look at this. It had not been looked at in the way that we had been hoping for, and that is to design a clinical trial where you're looking at patients that have a triglyceride in that sweet spot of atherosclerosis, which is somewhere in the 200 to 500 range, that sweet spot, to determine whether low triglycerides in that range on top of standard of care therapies reduces the risk of cardiovascular events. Hence Amarin steps up to the plate and does the study.

BY MR. CLEMENT:

Q At about 500?

A No, we're now talking about between 200 to 500, the REDUCE-IT study. That's the study.

Q Okay.

A 500 is pancreatitis -- above 500 we're talking about pancreatitis. Below 500 -- 200 to 500 is really the sweet spot of atherosclerosis.

Q So above 500, you're really worried about pancreatitis; is that --

A So the way -- the way it works is that the numbers -- you know, you take -- and these are approximations for each 100-milligram per deciliter increment above 500, give or take again,

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the risk of pancreatitis goes up approximately 4 percent.

So not everybody that has a triglyceride of a thousand will develop a pancreatitis, but there is an increased risk.

Q So is it that above 500 the risk of pancreatitis becomes greater than the risk of atherosclerosis?

A If the triglyceride gets to a level of nearing approximating a thousand.

Q Okay.

A Eight -- even 800 -- I would say starting somewhere in that 800 to a thousand range.

Q Now, do you . . .

Now, in paragraph 35 of your report -- I think this is kind of what we were just talking about that once the triglycerides are decreased below the critical level -- and you say about 500 mgs per dl?

A Right. And the adult treatment panel basically made those cut points for a reason.

Q But here you say "about"; right?

A Yeah, about. I mean, that -- that's a -- so generally speaking, triglycerides are not

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a primary treatment for clinicians unless levels exceed 500. Then it becomes the primary therapy in order to lower those triglycerides and presumably reduce their risk.

Q Do you treat a patient who presents to you with a triglyceride level of 495 differently than you treat one who has a level of 501?

A Yeah.

MR. KENNEDY: Objection to form.

THE WITNESS: So, again, the number there is -- gives you and gives any person who treats patients some reference to use. These are guidelines, and if you treat patients, you would come up with kind of an idea of who the patient -- which patients pose most risk.

So am I going to differentiate between a 499 and a 501 -- of course not. But it kind of puts me in the ballpark of where I need to be a bit concerned with respect to that issue of very high triglycerides than I would be if the level was 100.

BY MR. CLEMENT:

Q So if you turn to the patent, the '728 patent which I think you have there --

A I do.

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Q -- and you look at column 2 --
A Yes.
Q -- and do you see there in lines 7 through 11?
A Yes.
Q And it says -- is this kind of like what you're saying that when they have numerical values in here, right, it says they're stated as approximations as though the minimum and maximum value within the stated range were both preceded by the word "about"?
A Right.
Q Okay. Even some of the claims, right, I think, say about 500 as opposed to just 500, right, if you look at claim 19 of the '728 patent.
A Yes, I would agree with that.
Q And would you say "about" is, what, plus or minus 10 percent? I mean, do you have a figure in your head?
A Give or take, 10 percent is reasonable.
MR. CLEMENT: All right. Is this a good time for a break?
MR. KENNEDY: Sure.
MR. CLEMENT: Can we go off the record?
THE VIDEOGRAPHER: The time is

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11:08 a.m. We're going off the record.
(Recess -- 11:08 a.m.)
(After recess -- 11:24 a.m.)
THE VIDEOGRAPHER: The time is 11:24 a.m. This begins media unit number 3 and on the record.
Please proceed, Counsel.
BY MR. CLEMENT:
Q Thank you.
Dr. Miller, in paragraph 37 of your report -- not your report, your declaration -- I'm sorry.
A Yes.
Q You talk about in 2009 there being recognized problems for SHTG -- VH -- what was the acronym we were using VHTG?
A VHTG.
Q Severe and very would be the same?
A Sure.
Q All right. So you're talking about in 2009 there's some recognized problems; right?
A Yes.
Q And you cite to some labels, some package inserts, right, in support of that?
A I believe I do, yes.

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Q You can look right there on yours. Correct?
A Yes.
Q And that's all you cite in that paragraph; right?
A Yes.
MR. CLEMENT: Okay. Let's mark as Exhibit Number 16 a document with Bates range 3058234 through 3059940.
(Miller Deposition Exhibit 16 was marked for identification and attached to the transcript.)
BY MR. CLEMENT:
Q And that's -- Dr. Miller, I'll represent to you those are the -- that's the -- was Exhibit 18 to your declaration -- that's excerpts to the '727 file history.
A Okay.
Q And that's what you cited to in paragraph 37 of your report; right?
A I believe so.
Q Okay. Let's turn to the first one, package insert for TriCor, which is at 3059121. Maybe it starts at 9120. Okay. And that's the package insert for TriCore that you relied on;

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right?
A Yes. I might need a magnifying glass, though.
Q Sorry. I -- it's the way it's printed. So if you look at page 9123 for a second, in the bottom right you see it says, Revised: October 2010.
A Yes.
Q So it's after the 2009 date; correct?
A Yes.
Q And, so, this is not -- this document that you have here as your exhibit or that you relied on is not something a person of ordinary skill in the art would have known about; correct?
MR. KENNEDY: Objection to form.
THE WITNESS: Right. But I would also want to look and see the prior -- the prior version because there might have been no substantial change to this.
BY MR. CLEMENT:
Q But we don't know; right?
A I don't have that one.
Q Right. Because you didn't attach it to your declaration; right? Correct?
A Correct.

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Q You did not rely on an earlier version for your declaration; right?
A That is correct.
Q And you rely specifically on page 2 of this package insert, right, which is at 9121?
A Yes.
Q That's what you cite to -- 9121 is what you cite to in paragraph 37 of your declaration; right?
A Correct.
Q Do you recall what exactly you were relying on on 9121?
A Let's see what it says here.
(Witness reviews document.)
So I have to look at these tables. It would be nice to . . .
(Witness continues reviewing document.)
So there's one table here in patients -- in Table 2 where LDL levels go up from baseline of 120 to a baseline of 128, and then right below that are baseline LDL levels in -- with triglycerides of 5- to 1500 where LDL goes up 45 percent.
Q But this -- this -- this product, TriCor, it's not contraindicated in people with

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VHTG; right?
A I -- it is not contraindicated in people with VHTG.
Remember, though, the first goal is to try to reduce the likelihood that very high triglyceride levels will in and of itself be problematic.
Q Okay. But, again, it's not contraindicated --
A No.
Q -- and you prescribe it with people with VHTG; right?
A Yes.
Q Okay. Let's go to the next label for Lopid, 305 -- page 9106.
A And -- and I -- I should say that I prescribe in 2009, right, at the time of -- we're talking about when these prescriptions --
Q Okay.
A When we talk about prescriptions as opposed to now. I just want to clarify that.
Q So if you can turn to three -- page 9106, same exhibit.
I'm sorry. We're going to go through each of these labels --

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A Okay.
Q -- package inserts that you discussed in paragraph 37 of your declaration.
A Uh-huh.
Q Okay. And this one is for Lopid; right?
A Yes.
Q Which is gemfibrozil?
A Correct.
Q And if you turn to page 118, the bottom left, do you see it's a 2000 -- September 2010 document?
A I see that.
Q That's after the 2009 date; right?
A That's what it says.
Q So this document would not have been available to the person of ordinary skill in the art in 2009; right?
A Well, I don't know. If you look at page 100, it says revised July 2001. So I'm not sure -- it says additional adverse reactions have been reported including cholecystitis and cholelithiasis. To me, that suggests that only that paragraph on page 101 was from 2010, but the one from 100 was revised in 2001, and everything

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preceding that would be related to 2001 time frame.
Q What page are you on?
A If you look at page 9118 --
Q Right.
A -- so that said -- now go to 9117. At the top of 9117 it says, Revised July 2001.
So my interpretation would be that unless there are other revisions above that that everything related to Exhibit B, Lopid, through page 9117 would -- would be valid through July 2001; and then the additional wordage regarding -- the additional changes and adverse reactions were added in, and that revision came through in September of 2010.
Q Okay. But we don't know because we don't have the 2001 label here; right?
A Well, but it says, Revised July 2001, incorporating all -- all this information.
So to me it would seem that all this information related to -- to 2001 or before.
Q Okay. Now, you cite this document for saying that certain fibrate drugs increase the risk of rhabdomo- -- rhabdomyol- -- myol- -- I guess you can pronounce it.

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A Rhabdomyolysis.
Q Thank you.
When combined with a statin; right?
A Correct.
Q Okay. If we turn to page 110 of this document in the contraindications section, it only lists one statin, right, in the contraindication section; correct?
A Combination of therapy with cerivastatin due to the increased risk of myopathy and rhabdo.
Q And cerivastatin, that was a Bayer drug?
A That's correct.
Q Baycol?
A Correct.
Q No longer on the market; right?
A Correct.
Q And no other medications -- statins are indicated in the contraindications; right?
A None were identified in the contraindications; although, I will tell you for POSAs treating patients in this time frame that it would be a concern combining Lopid with any statin.

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Q Okay. But that's not what it says here in the contraindications --
A No --
Q -- right?
A -- that's true.
Q There are other statins out there; correct?
A That's correct.
Q And some of them metabolize or interact with drugs differently?
A Yes.
Q Kind of like the pitavastatin you were mentioning this morning that you were involved in?
A That's correct.
Q Okay. Let's turn to 3059150, the next one, Lovaza. And if you look on page 9150, it says, Revised: December 2010.
A I see that.
Q So this one also was not available to the person of ordinary skill in the art in 2009; correct?
A Well, again, it's unclear to me what was revised in 2010.
Q Well, if you go --
A And --

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Q I'm sorry. Go ahead. Finish. I didn't mean to speak over you.
A And --
Q I mean, we can look --
A That's what I'm --
Q We can look at page 159, and that 2010 date is also there; right? And we can look at on 163, and that 2010 --
A Right.
Q -- date is there?
So this document itself, right, that you were relying on, this wasn't -- this document was not available to the person of ordinary skill in the art in 2009; right?
A Well, not the way it is written. And -- and for -- for all intents and purposes, there may have just been one paragraph that was revised. I have to look at the 2009 --
Q But you didn't provide us the 2009 label; right?
A I did not.
Q Okay. And you didn't rely on the 2009 label in your paragraph 37; right? You relied on this one?
A (Witness reviews document.)

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I relied on this (indicating) document.
Q Okay. Is there anything in this document that says you shouldn't treat patients with triglyceride levels of 500 to 1500 mgs per dl with Lovaza?
MR. KENNEDY: Objection to form.
THE WITNESS: No.
But, again, we have to put things in perspective, and that perspective is when a patient has very high triglyceride, the first order of treatment is to lower VHTG, and then from there we take additional steps. But the first order is to lower the triglyceride.
BY MR. CLEMENT:
Q Okay. And if you look -- you rely on page 157; right? And this is talking about patients with very high triglyceride levels, above 500 mgs per dl; right?
A Yes.
Q It doesn't say don't treat patients with Lovaza. All it says is patient should be monitored; right?
A Yes.
Q Now let's look at Niaspan, 3059139. Can you turn to 9139, please?

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MR. KENNEDY: It's back the other way.
BY MR. CLEMENT:
Q Okay. And this is the fourth package insert you rely on for paragraph 37; correct?
A Yes.
Q And this is also a 2010 revision document; right?
A Yes.
Q So this one wouldn't have been available to the person of ordinary skill of the art in 2009; correct?
A Well, again, I don't know that. We know that there was clearly information that was available, and the extent to which there might have been changes between 2009 or 2008 and 2010 whatever, previous version is, is -- is unclear.
Q Right.
But, again, we don't know because you didn't provide that in your declaration; right? What you provided was a 2010 re- -- revision; correct?
A That's correct.
Q And the 2010 revision, the document here that's before us on 9139 through 9148, that was not -- this document as it exists here was not

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available to the person of ordinary skill in the art in 2009; right?
A Well, the document wasn't -- may have not been in its exact form, but it was certainly recognized that LDL increases did exist with some of these agents including gemfibrozil, including fenofibrate. And some of the side effects I've alluded to with niacin have been known well before 2009 -- well before then.
Q Right. But you didn't provide that document to us. You provided a 2010 document that was after the date of the patent filing; right?
A Well, but, again, I can -- my experience in this field dating back to the 1980s, I could verify that these problems existed well before this time frame.
Q You could have verified that before you submitted your declaration or before you submitted your reply declaration and you didn't; correct?
A Well, I think part of the declaration also attests to my level of experience in the field which predates 2009.
Q Understood.
But you relied on this document for your statement in paragraph 37, and this document

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is dated after 2009; right?
A The document is dated after 2009.
Q Okay. Now --
A -- I will agree.
Q -- let's look at the document. You relied on -- I guess, on -- you say in paragraph 57 you rely on page -- I'm sorry. You say in paragraph 37 of your declaration you rely on pages 139 to 148 of this document; right?
I'm just wondering what exactly in this document you're relying on?
A If you'll give me just one minute to review it.
Q Sure.
A (Witness reviews document.)
So the discussion with respect to niacin is the issues of the side effects, and those issues are described on 146, 147, 148.
Q But all drugs have side effects; right?
MR. KENNEDY: Object.
THE WITNESS: Niacin has side effects that can be intolerable to patients, more than the other triglyceride-lowering drugs.
BY MR. CLEMENT:
Q Okay. They all -- again, all drugs

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have side effects; right?
MR. KENNEDY: Same objection.
THE WITNESS: There is a difference in tolerability of some drugs compared to others. Niacin often is not tolerated in a sizeable percentage of patients whereas other medications to treat very high triglyceride levels are.
BY MR. CLEMENT:
Q Now --
A So, yes, all drugs have side effects, but the degree and extent of side effects that may limit its usage is different.
Q Okay. But it's not contraindicated with patients who have VHTG; right?
A No, it was -- at the time it was recommended for patients with VHTG.
Q Okay. Now, you -- I think we talked earlier about Epadel?
A Yes.
Q And that was a Japanese medication; right?
A That -- that was my understanding.
Q Now, you don't cite to Epadel in your declaration as all; right?
A Correct. It's outside of the scope of

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my declaration.
Q Why is it outside the scope of your declaration?
A It just wasn't cited.
Q Okay. We -- did you not cite it because it was a Japanese drug instead of a U.S. drug or --
A I -- I really haven't given it that much thought.
MR. CLEMENT: Let's mark as Miller 16 --
THE COURT REPORTER: Seventeen.
MR. CLEMENT: -- 17, sorry, a document with defendants Bates range 8961 through 8969.
(Miller Deposition Exhibit 17 was marked for identification and attached to the transcript.)
BY MR. CLEMENT:
Q Dr. Mill- -- Dr. Miller, have you ever seen this document before?
A No.
Q It's dated January 2007.
A I see that.
Q It's indicated for hyperlipidemia, page 2?

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A In Japan, I take it?
Q Yeah.
Correct?
A Yes.
Q And it says to increase the dose when excess triglycerides are present; right?
MR. KENNEDY: Objection: outside the scope of his opinions.
THE WITNESS: It's outside the scope --
MR. KENNEDY: I mean --
THE WITNESS: -- of my opinions.
MR. KENNEDY: -- you can answer. I have to make my objections.
BY MR. CLEMENT:
Q You can answer.
MR. KENNEDY: You can answer if you can.
THE WITNESS: That's what it says.
BY MR. CLEMENT:
Q And, again, Epadel was pure icosapent?
MR. KENNEDY: Objection to form; outside the scope.
THE WITNESS: It's ethyl eicosapentaenoic acid.
BY MR. CLEMENT:

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Q With a high purity?
MR. KENNEDY: Same objections.
THE WITNESS: I don't know what the purity is.
BY MR. CLEMENT:
Q Now have you ever been involved in a clinical study?
A I have.
Q And have you ever drafted a clinical protocol?
A I have not.
Q Do you know what the purpose of --
A Oh, let -- let me take that back.
Q Okay.
A Clinical -- could you be a little more specific?
Q I guess I -- protocol for a clinical study?
A I've done studies but not drug-based studies. Well, I take that back. I did do -- I did do an investigator initiated study a number of years ago, so I did draft that protocol.
Q What -- so what is a protocol? What's the purpose of it?
A Well, the purpose of a protocol is to

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really have set -- a set format and blueprint for how you would conduct a trial, and that would include a number of variables.
Q Are there different types of studies that you can conduct in the clinical -- as far as a clinical study goes?
A Well, of course there are studies that are observational in nature whereas there are studies that are treatment designed.
Q Okay. And what about, like, a double-blind study? Have you ever heard of that?
A Yes.
Q Okay. And, in fact, on your CV, I think on page 12, you talk about a double-blind study.
You can check on your CV.
A Yes.
Q What is a -- what does the "double" refer to?
A Well, the double refers to maintaining a blinding status from both the standpoint of the patient and the standpoint of the investigators/coordinators conducting the trial.
Q So -- and blind refers to what?
A Neither party knows whether the

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treatment is active or inactive.
Q You don't know if you're taking the medication or a placebo?
A Correct.
Q And is that different than an open-label study?
A Yes.
Q How is that different from an open-label study?
A In an open-label study, the medication is provided and the patient and investigator generally know that the medication is being used.
Q Right.
And what about a placebo-controlled study? Do you know what that means?
I think in your -- on your -- on your -- your CV you talk about double-blind and placebo-controlled. That's where I'm getting it from.
A Right. A placebo-controlled study would be that the comparative nature includes the active compound versus the inactive compound.
Q In order to have an inactive compound, some of the subjects of the study are actually taking a pill that have -- just doesn't have

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medicament in it; correct?
A Yeah, ideally you'd want to take -- for all intents and purposes, you would want the shell to resemble each other -- of course the shell being inactive whether it's pharmaceutical grade or nonpharmaceutical grade, but the composition inside is what differentiates.
Q The person doesn't know looking at it from the outside whether they have the placebo on the one hand or the active medication in the other; right?
A Correct.
Q But they're actually -- even the ones who are the controlled part of the study getting a placebo, they're actually swallowing a pill?
A Well, the -- whether it's in a clinical trial or in practice, it's more than just swallowing a pill. It's being advised what to take and when to take it, so it's administering from the caregiver. And ultimately one part of that process is that the patient or the subject if it's a clinical trial will take the pill -- will swallow the pill.
Q Swallow the pill, okay.
A If -- if it is -- depending upon, I

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mean, how it is prescribed, right, because I haven't seen too many double-blind studies where there -- well, it could be injectable --
Q Okay.
A -- there are a lot of injectable studies out there.
Q That's fair enough. I'm talking about an oral.
A Right.
Q Okay. All right. What about a parallel -- what's a -- I guess -- have you ever heard of a crossover study? Let's start there.
A Yes.
Q Do you know what a crossover study is?
A Yes.
Q Can you --
A A crossover study is when the volunteers are assigned to more than one arm, and they crossover. So they will go on, let's say, medication A for a period of time, have a washout period, then medication B for a period of time, have a washout.
And that's usually what we refer to as randomized and counterbalanced which means that the volunteer doesn't know which phase -- which

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medication, and it's counterbalanced so that if you look at 50 subjects, 25 of them get medication A first, and 25 of them will get medication B first.
Q When you said there's two arms, what do you mean by the arms?
A The arms is -- is really that portion of the study where that assignment of medication is -- is identified or blinded, if you will.
Q And is that different than a parallel study?
A Yeah, I don't do -- I've not really participated too much in parallel studies.
Q I think on page 16 of your CV you talk about a grant that was a -- it says, Parallel group. So, I don't know, maybe that wasn't a parallel study. Maybe I'm misreading --
A That's not a parallel study.
Q What did you mean by "parallel group" there, though. Do you see that one, April 2005 to March 2007?
A Yes, I -- I -- I think it's just running them in parallel, so you're having patients receiving either the combination arm or receiving the atorvastatin only arm.

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Q So they're not crossed over? You get one --
A They're not --
Q -- arm or the other?
A -- crossed over; correct.
Q Okay. I guess, what knowledge -- do you consider you're an ex- -- strike that.
Do you consider yourself an expert in statistics?
A No.
Q Okay. Do you consider yourself knowledgeable about statistics?
MR. KENNEDY: Objection to form.
THE WITNESS: I usually will confer with a statistician in regard to studies that are conducted. Interpreting results of studies, I have some basic knowledge.
BY MR. CLEMENT:
Q Do you know what the concept of statistical significance is?
A Yes.
Q Okay. What is that to you?
A Well, it's usually related to trying to determine whether or not group A is different from group B, and oftentimes a study is powered to show

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that there's a significant difference of less than or equal to 5 percent which means less than 5 percent of the time you would see -- expect to see virtually the same value.
Q Okay. And do you know what a confidential interval is?
A Yes.
Q What is a confidence interval?
A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range.
Q And when you say that -- when you're looking at statistical significance, that's usually predefined what that level will be. You said 95 percent. Is it pre- -- usually predefined in the medical protocol what that level you're looking for is to determine whether it's statistically significant or not?
A As a general rule, you would predetermine -- you would power the study so that a statistician will do a calculation to determine the number of participants needed to see a difference between whatever your variables are.
Q And that's predetermined, right, you

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don't do that after you conduct the study; you do that before?
MR. KENNEDY: Objection to form.
THE WITNESS: Yeah, in some trials they actually have what we call an interim analysis. So you can make some changes although that -- that adversely affects your power -- I mean, that adversely -- right, so that does -- that does exist.
BY MR. CLEMENT:
Q Okay. Is that something you'd use a Bonferroni correction for? Do you know what a Bonferroni correction is?
A Yeah, I've seen Bonferroni, but I think it's somewhere along -- in that ballpark.
Q And does the type of statistics a statistician will use will depend on whether the data is normal or not normal?
A Yes.
Q Do you know why they use different tests?
A Yeah. Well, you know, in the sense of -- depends on if there's a normal distribution. So if -- if the distribution is -- is abnormal or highly variable, they may need to kind of tighten

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it up. And, so, they may use different forms of stats such as log transformation -- is one way to tighten it up.
Q Or Mann-Whitney?
A Or Mann-Whitney. There are a bunch of different --
Q Bunch --
A -- ones.
Q -- of ones, right.
And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary variable?
A (Witness nods head.)
Q I think nods of the head -- I just want to make sure the court reporter is getting that.
A Yes.
Q Thank you.
A And it depends on the specific study you're looking at. But primary efficacy -- well, there are lots of different outcomes you could talk about. In early phase trials you're looking at safety and efficacy. In more advanced stages you're looking at clinical outcomes. And, so, yes, an efficacy endpoint may be how you derived

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the blood pressure -- a degree of blood pressure lowering that might be anticipated. At higher stages you might look to see patients with blood pressure being placed on blood pressure medication A versus B may have a -- a reduction in cardiovascular events.

Q And might you use different significance levels for each of those different variables that you might look at? Is it always going to be .05 or --

A Yeah, it varies. I mean, typically -- traditionally in outcome studies .05 is the number, but it does vary. And if you're doing genetic studies, then sometimes it goes out to the order of magnitude of up to minus ten -- fifth to tenth power, so it depends on a lot of variables that -- that statisticians are familiar with.

Q Okay. Let's turn to paragraph 39 of your report. And in paragraph 39 -- are you there?

A I am here.

Q Great.

The third sentence you say, The methods developed by the inventors covered administering a high dose, 4 grams per day.

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A I'm sorry. I'm on -- is it -- I'm looking at page 39, but you're looking at --

Q Sorry. Paragraph 39.

A Paragraph 39.

Q Sorry.

Okay. You see the third sentence begins, The method -- methods developed by the inventors covered, and it goes on?

A (Witness nods head.)

Q Okay. What did you mean by "covered"?

Is that what the inventors claimed? I guess that's the question I'm trying to get to.

A Yeah, I think I'm -- the methods developed by the inventors covered administering this dose to very high TG patients.

Yeah, covered was -- that's how they solve the problem which is noted two sentences up.

Q Okay. Is that what they claimed, or was it something different?

A Well, the claimed composition is discussed a little bit beforehand, but in terms of -- of covered, I think I was referring to basically the administration of this medication that would result in -- in some of the changes here related to TG and ApoB.

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Q I guess, you know, you say here they cover this, and they say to very high TG patients receiving diet and lifestyle-change counseling.

And, I guess, where did you get that from, receiving diet and lifestyle-change counseling?

A Yes, so that was part of the MARINE study. In the MARINE study, patients get -- being considered for inclusion into the study needed to be first placed on a diet and lifestyle change. So they received counseling, and they received the therapeutic, lifestyle-change counseling.

Q Okay. That was in the studies. Do you equate the patent and the study?

MR. KENNEDY: Objection to form.

THE WITNESS: No, a patent is -- is -- relies upon the study, but -- and the results obtained in the study in formulating the patent. But a study and the patent are not one and the same.

BY MR. CLEMENT:

Q Okay. Because in claim 1 or any of the claims in the '728 or any of the patents-in-suit, does that language exist, "diet and lifestyle-change counseling"?

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MR. KENNEDY: Objection to form.

THE WITNESS: I would have to review that.

BY MR. CLEMENT:

Q Well, take a look at at least the '728 patent since we have that here.

A Right. So if we look at claim 1 in the '728 patent, the focus here is on concomitant lipid-altering therapy, which would not be inclusive of lifestyle therapy. It's distinct because lifestyle therapy had already been instituted, at least -- everybody goes on lifestyle therapy. That -- that's a given. And, so, this is beyond that point. It's patients that have residual triglyceride elevation between 5- to 1500.

Q Okay. So you're saying that everyone in claim 1 was on lifestyle therapy; is that what you're saying?

MR. KENNEDY: Objection to form.

THE WITNESS: I'm not -- I'm referring to everybody in the MARINE study who participated in that clinical trial were placed on diet and lifestyle therapy in order to determine whether they would still be potentially eligible to

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participate in the trial.
BY MR. CLEMENT:
Q I think we're in agreement on that.
But I guess my question is for the claim, right -- is this claim trying to claim what was in that example?
MR. KENNEDY: Objection to form.
THE WITNESS: It's really looking at patients and -- and my -- my interpretation is that it is looking at patients who we encounter in practice who have a fasting baseline level in this range, viewed in the very high triglyceride range.
BY MR. CLEMENT:
Q So in the patients who you encounter, they may or may not be on a lifestyle counseling, right, the first time you see them?
A Correct.
Q Right.
And the first therapy -- the first line of therapy, am I correct, would be put them on some sort of diet and exercise regimen?
MR. KENNEDY: Objection to form.
THE WITNESS: The first line of therapy for any patient we see -- it doesn't have to be very high triglyceride patient; it's any patient

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that we would see -- we're going to recommend lifestyle therapy.
So it doesn't matter if they're -- what they're -- if their triglyceride is normal or abnormal. They may have high -- some degree of elevated blood pressure. They're going to go on lifestyle therapy. They may have some degree of elevated blood glucose. They're going to go on lifestyle therapy. They may have some degree of obesity and want to lose weight. They are going to go on lifestyle therapy.
The point being that "lifestyle therapy" is a very broad term. Patients should go on lifestyle therapy. Did -- it's -- it's really initial management of any patient that has any cardiovascular risk factor.
BY MR. CLEMENT:
Q But that includes VH -- VHTG patients that present to you. The first thing you'll do for therapy is put them -- give them ther- -- lifestyle counseling, right --
MR. KENNEDY: Objection.
BY MR. CLEMENT:
Q -- diet and exercise regime?
MR. KENNEDY: Objection to form.

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THE WITNESS: So it really does depend on the clinical scenario. So as I've said, they automatically -- they all go on it, and then question is are we also going to institute pharmacologic measures at that time. So I think that's maybe where that --
BY MR. CLEMENT:
Q Okay. But, again --
A They all go on -- they all go on lifestyle therapy.
Q Including those with triglyceride levels above 500 mgs per dl?
A They all go -- I refer to it as a therapeutic lifestyle change. It's something that's not unique. It's broad-based. It's for any patient. And it's different than blood pressure therapy, blood pressure medication, lipid-lowering therapy, lipid-lowering medication, hypoglycemic agents, glucose-lowering therapies.
Q I understand all of that.
I guess my question to you, though, remains, the person who comes in and their lipid levels are -- they have a triglyceride level of 500 -- more than 500 mgs per dl. The first thing you're going to -- the first form of therapy that

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you're going to tell them to do is to go on some sort of diet and exercise regiment; correct?
MR. KENNEDY: Objection to form.
THE WITNESS: Yeah. You know, I look at it as a lifestyle change.
BY MR. CLEMENT:
Q Okay.
A It's a lifestyle change.
Q Okay.
A That's what it is.
Q That's fair enough. Okay.
Now, you say here in 39, also -- you talk about the claimed composition. I mean, I guess, I just want to make sure we're on the same ballpark. My understanding is all the patents-in-suit, they claim a method of treating; right?
A Yes.
Q Okay. They're not claiming the composition, per se?
A No.
Q Right.
A It's method of treatment.
Q Okay. Now, also if you look at claim 1 of the '728 patent --

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A Yes.
Q -- and do you see about one, two, three, four, five lines down in that claim there's the term "pharmaceutical composition"?
A Yes.
Q All right. Do you have knowledge as to whether the parties are disputing the meaning of that term?
A I don't believe I commented that in my --
Q All right. That's going to be my next question.
A Yeah.
Q I mean, have you given any opinions on the term "pharmaceutical composition" in your declaration?
A I don't believe so.
Q And in your reply declaration?
A I don't believe so.
Q And you weren't asked to give opinions by counsel on the term "pharmaceutical composition" --
A I am not --
Q -- right?
A -- not there.

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Q And are you a formulator?
A I am not.
Q And you don't consider yourself an expert in formulation; right?
A That is correct.
Q And in claim 1 there, right, I think we -- I might have asked this already, but -- well, strike that.
Now, let's assume the pa- -- patient comes with you, right, at a triglyceride level of above 500 mgs per dl; right?
A Yes.
Q Let's -- let's take this back to 2009 --
A Okay.
Q -- okay?
The first thing you're going to do is say lifestyle changes; right?
A That is part and parcel of our discussion, yes.
Q And then if that doesn't take care of the problem, right, then you might prescribe also a medication; right?
A Not necessarily.
Q Not necessarily, okay.

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A I may -- I may -- it depends. It depends on the scenario. Certainly if they're coming to see me and they have a history of pancreatitis and they're not taking any medication at that time, I'm going to put them on medication --
Q Okay.
A -- at that time --
Q And --
A -- triglyceride-lowering medication.
Q And could that include statins?
A Probably not.
Q Probably not, okay.
A Not in that specific scenario. Now, there are other scenarios where that might be the case, but not the one we just discussed.
Q Okay. But there are cases where you might prescribe statins; right? That would be -- I guess, my question -- do you agree with me that statins would be a concomitant lipid-altering therapy?
MR. KENNEDY: Objection to form.
THE WITNESS: It is a concomitant lipid-altering therapy as -- as stated here combined with, here, ethyl eicosapentaenoic --

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ethyl icosapent.
BY MR. CLEMENT:
Q Okay. Just -- so you're saying that someone who is also on icosapent, if you were to prescribe them a statin in addition to the icosapent you would agree that is a concomitant lipid-altering therapy; correct?
A Yes.
Q Do you know if the patent covers methods for people not receiving diet and lifestyle change counseling?
MR. KENNEDY: Objection to form.
THE WITNESS: Diet and lifestyle is --
BY MR. CLEMENT:
Q You know what -- let me --
A Yeah. Sorry.
Q -- rephrase that. Okay. Let me strike that and rephrase.
Do you know if the patent claims methods for people -- patients not receiving diet and lifestyle change counseling?
MR. KENNEDY: Objection to form.
THE WITNESS: I would have to look at -- at the patents to see if that wording is used.

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BY MR. CLEMENT:
Q Okay. Well, if you'd look to claim, let's say, 15 of the '728.
A I see it.
Q All right. There it says the subject is on a -- is consuming a western diet; right?
A (Witness nods head.)
Q So if they're on a western -- can you tell me -- do you have -- do you have -- strike that.
Do you agree with me that's what that claim is saying?
A Yes.
Q Do you know what a western diet is?
A I do.
Q And what is a western diet?
A The west --
MR. KENNEDY: Objection to form.
Sorry. Go ahead.
THE WITNESS: A western diet is a diet that is consumed in westernized societies that typically is unhealthy because it contains a fair amount of unhealthy fats and perhaps other processed foods with an associated elevated risk of heart disease compared to eastern diets which

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are generally healthier.
BY MR. CLEMENT:
Q Okay. And the patent actually says what a western diet is; right? If you turn to column 9, line 29 to 38, I guess it is.
A Yes, that -- that --
Q You'd agree with that definition in the patent?
A Yes.
Q And, so, someone who is consuming that diet is not on lipid-altering therapy; right?
MR. KENNEDY: Objection.
MR. CLEMENT: I'm sorry. Thank you.
All right. Strike that.
BY MR. CLEMENT:
Q And, so, the person on a western diet is not, in your opinion, receiving therapeutic lifestyle counseling; right?
A (Witness reviews document.)
The western diet is not a diet that I would prescribe to my patients.
Q But it is within the scope of claim 1 of the patent, right, because it's in claim 15 which depends on claim 1?
MR. KENNEDY: Objection: Outside the

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scope.
THE WITNESS: I see that, and -- and -- and, so, the idea, again, is that you could recommend a medication in patients who are coming with elevated triglyceride even if they are on a western diet.
BY MR. CLEMENT:
Q And that would be different than the example in patent or the MARINE study, right, because there everybody was on the lifestyle counseling; right?
MR. KENNEDY: Objection to form.
THE WITNESS: That is different than what was used in MARINE.
BY MR. CLEMENT:
Q And -- right. Okay.
And what's exam- -- the example of the patent; right?
A Well --
MR. KENNEDY: Same objection.
THE WITNESS: Yeah, as listed in 15.
BY MR. CLEMENT:
Q Okay.
MR. CLEMENT: Now, I'm going to mark the next exhibit which is going to be Miller 17 --

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18. And it's a document with defendants Bates range 10211 through 10225.
(Miller Deposition Exhibit 18 was marked for identification and attached to the transcript.)
BY MR. CLEMENT:
Q And Dr. Miller, can you -- let me know if you've ever seen this document?
A I have.
Q And this is one that you're an author on?
A I am.
Q This was published in 2007?
A It was, yes.
Q Okay. And it's with Terry Jacobson?
A Yes.
Q Who is Terry Jacobson?
A He is a colleague of mine who is based out of Atlanta. He is a cardiologist.
Q Would he be a person of ordinary skill in the art?
A Yes.
Q And an expert in the field that we're talking about?
A Yes.

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Q What about Ernst Schaefer?
A Yeah, Ernie is based out of the Bo- the Boston area, another --
Q And is he --
A -- physician -- another expert.
Q Would you consider him a person of ordinary skill in the art --
A Yes.
Q -- at least a person of ordinary skill --
A Yes.
Q -- in the art as you defined?
A Yes.
Q What about as an expert?
A He's an expert.
Q Okay. Is -- is this a review article?
A Yes.
Q And what does that mean, it's a review article?
A Basically reviews the substantive information at the time as it relates to the topic being evaluated.
Q All right. And you don't do any additional clinical research; you're just looking at what's been published before?

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A Right. There -- there are no new -- or no new studies in here or no new original studies.
Q And what was this article about?
A Basically the issue as it relates to cardiovascular disease and elevated triglycerides.
Q And on page 764, the lower left hand column, you talk about a meta-analysis; right?
A (Witness nods head.)
Q Is that what was conducted here, a meta-analysis?
A Well, not conducted for this. We reviewed the data that included meta-analysis.
Q Meta-analysis, okay.
And a "meta-analysis" -- can you define that for us?
A Yeah. So meta-analysis is really designed to enhance the stature -- the recognition of a finding that -- that now incorporates a number of studies and a number of additional subjects.
For example, you could have several clinical trials that may trend towards significance, and now you -- and they are studying relatively similar topic, and now you're putting them altogether. So now you have more power to

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see changes.
So the small scale studies may have not really shown you a lot, but now when you put it altogether in a meta-analysis, it can drive one way or the other the -- the thoughts or the hypothesis that were being generated.
Q Okay. And on the very first page of this article of yours, you have a results section; right?
A Yes.
Q And you say, Concern over the increasing rate of hypertriglyceridemia; right? Is that 500 or above --
A No.
Q -- mgs per dl?
A Not necessarily.
Q No, no?
A It's not, let's say, very high triglycerides. Hypertriglyceridemia can be defined as a triglyceride as low as 200.
Q But it could also include people above 500?
A Not -- not in this context.
Q Not in this context?
A No.

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Q Okay.
But they do talk about lipid-lowering agents that could be used for hypertriglyceridemia, right, in this results section?
A Yes.
Q And that includes statins, fibrates, niacin, thiazolidinediones and prescription omega-3 fatty acids?
A Yes.
Q And it says, Along with lifestyle changes; right?
A Yes.
Q And you don't -- there's no -- in these results, there's no mention of any problems with statins or fibrates or niacin; right?
MR. KENNEDY: Objection to form.
THE WITNESS: Not in this paragraph, no.
BY MR. CLEMENT:
Q And on page 766, right, you talk about treatment recommendations; right?
A Yes.
Q Do you see that?
And these are recommendations by virtue

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of this publication you were trying to inform doctors about; correct?
A Yeah, we were just kind of summarizing the available information.
Q If you go to the next page, 767 where you talk about triglyceride-lowering therapy, lifestyle modification?
A Yes.
Q And you note there, right, that weight loss and exerc- -- increased exercise are the cornerstones of TG-lowering therapy; right?
A As they are for blood pressure reduction, glucose reduction, weight loss, LDL reduction, weight loss and increased exercise are the corner stones of all -- virtually all therapies to reduce heart disease risk.
Q Okay.
A So it's not unique to triglycerides. It is a broad -- it's broad-based, and it is part and parcel of treatment for everybody. It is not specifically lipid-lowering therapy. I would not classify it as lipid-lowering therapy as I would for ezetimibe, a lipid-lowering therapy -- ezetimibe to lower LDL or statins to lower LDL or fibrates to lower TG. So difference --

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Q Understood.
A But it is -- but it is -- it is the cornerstone of all preventative types of therapies.
Q Understood.
But here your sentence says, Weight loss and increased exercise are the cornerstones of TG-lowering therapy. So here you were specifically talking about T- -- triglyceride lowering; right?
A Because it's a triglyceride paper. If this was an LDL paper, I would have said weight loss and increased exercise are the cornerstone of LDL-lowering --
Q Very --
A -- therapy.
Q Very well, but that's all -- I understand.
I'm just saying --
A Okay. I just want to --
Q -- do --
A -- put it in perspective.
Q But you agree with that statement sitting here today, right, that weight loss and increased exercise are the cornerstones of

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TG-lowering therapy, right, true then and true now?
A Yeah.
Q Okay. And that would include for severe hypertriglyceridemia in addition to hyp- -- just general hypertriglyceridemia; correct?
MR. KENNEDY: Objection to form.
THE WITNESS: Yeah, severe hypertriglyceridemia is a -- is a -- a little bit -- while we -- while we certainly recommend weight loss and increased exercise, more often than not we would need to highly consider the use of a lipid or a triglyceride-lowering medication.
BY MR. CLEMENT:
Q In addition to the --
A Well --
Q -- diet and exercise regiment; right?
A Diet and exercise is -- is exclusive to that. We -- we -- that -- that is broad-based. We recommend that to everybody. That is not what I would refer to as lipid-lowering medication.
And, so, in patients who have very high triglycerides, above 500, more often than not they will need to go on medication and diet. While we would certainly want them to employ therapeutic

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lifestyle changes, more often than not they will also need medication.
Q Okay. That's fair. Then on the next page you talk about -- on page 768, fibrates; right?
A Yes.
Q And these are recommended therapies; right -- treatment recommendations?
A In 2009, that is correct.
Q Yeah.
And no mention of rhabdomyolysis here; right?
A I would actually have to look at the rest of the article to see if it's in here, but not in that paragraph.
Q And niacin is also here as a recommended therapy?
A Actually, I -- if you go to page 770, under the fibrate section and that paragraph, there is a statement. We say, A review of reports in the FDA's Adverse Event Reporting System found when these agents were coadministered with the statin the rate of rhabdomyolysis was 15 times higher, and this is with gemfibrozil than with fenofibrate.

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Q Okay. But it also says on page 770, right, in the paragraph 70 beginning, Gemfibrozil and fenofibrate, that they're commonly prescribed fibrates in the U.S.; right?
A Yes.
Q And then it says, These agents are generally well tolerated; right?
A Generally well tolerated, right, but it -- it doesn't take away from the concern as a physician -- the first thing we learn in medical school is "primum non nocere," first do no harm.
So even though these medications and others are well tolerated, we always have to take into consideration the possibility of harm, and hence that has to be included in a review paper or any other paper.
Q That's -- that's true of any medication, right, first do no harm. You don't want to -- you don't want to give them something that could just be an allergic rela- -- reaction to one of the ingredients; right? You want to -- you don't want to do any harm. No question about it -- that's a given.
But this says they're generally well tolerated; right?

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A Generally well tolerated, yeah, sure.
MR. CLEMENT: All right. Why don't we break for lunch.
THE VIDEOGRAPHER: The time is 12:29. This concludes tape number 3.
(Recess -- 12:29 p.m.)
(After recess -- 1:15 p.m.)
THE VIDEOGRAPHER: The time is 1:15 p.m. This begins tape number 4. We're on the record.
Please proceed, Counsel.
MR. CLEMENT: Okay. I will have the court reporter mark an AHA Scientific Statement article authored by Michael Miller, Exhibit 19.
(Miller Deposition Exhibit 19 was marked for identification and attached to the transcript.)
BY MR. CLEMENT:
Q Okay. Dr. Miller, have you ever seen what's been put before you as Miller Exhibit 19?
A Yes.
Q And that's a -- is that an article -- would you call that an article?
A It's really a -- a summary statement from the American Heart Association.

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Q And you're listed as the chair?
A Correct.
Q Okay. And there's a Neil Stone also on this --
A Yes.
Q -- article --
A Yes.
Q -- or statement, I should say.
A Yes.
Q Who is Neil Stone?
A Neil Stone is a professor at Northwestern who is also the chair of the national guidelines 2013, American -- AHA/ACC.
Q And would you consider him as a person of ordinary skill in the art?
A Yes.
Q And as an expert?
A Yes.
Q How about Christie Ballantyne?
A Christie Ballantyne is -- is in -- at Baylor in Houston.
Q And is she a --
A It's a he.
Q It's a he. Sorry.
And is he a person --

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A Yes.
Q -- you would consider a person of ordinary skill in the art?
A Yes.
Q And an expert?
A Yes.
Q And the same questions for Vera Bittner?
A Vera is over in Alabama, and, yes, she's an expert.
Q And at least a person of ordinary skill in the art as you've defined; right?
A Correct.
Q And how about Michael Criqui?
A Mike is in San Diego, and, yes, he is, also.
Q At least a person of ordinary skill in the art?
A Yes.
Q And what Henry Ginsberg?
A Henry is in New York and one of a number of New Yorkers who are experts in this field.
Q And Anne Goldberg?
A Anne Goldberg is in WashU in St. Louis

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where my daughters go next year. And --
Q Congratulations.
A Thank you.
And, yes, she is an expert.
Q What about William James?
A Bill Howard, he's in Wa- -- he's in Washington. He may be retired now, but he was viewed as an expert.
Q And Marc Jacobson, he was on the article with you before?
A That was Terry.
Q Terry, okay.
A But Marc and Kris and Terry and Moshe and Ted are -- Subramanian would all be viewed as experts.
Q So Terry Lennie would be viewed as a person of ordinary skill?
A Yes.
Q And same as Moshe Levi?
A Yes.
Q Same as Theodore Mazzone?
A Ted Mazzone, yes.
Q And also Subramanian Pennathur?
A Subramanian, yes.
Q All right. And this article is dated

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2011; right?
A Yes.
Q Okay. You can put that away.
In your review of the patent, the '728 patent -- let's stick with that one -- did that describe a completed study or a -- just the protocol for a study?
A Well, it's -- it's a -- a protocol for a study, and I don't know where that study stood at the time of the filing, but ultimately it became very important.
Q Okay. And that was known as the MARINE study?
A Yes.
Q Okay. If we -- do we have -- do you have the '727 file wrapper excerpts there?
Do you have the '727 patent file wrapper?
MR. KENNEDY: Is it Exhibit 16 or --
MR. CLEMENT: I'm trying to remember what I marked it as.
MR. KENNEDY: Yeah, I mean, I have the Bays declaration if that's what you're talking about.
MR. CLEMENT: It should be the whole

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document, the excerpts. No? It should start with -- yeah, it starts with the Bays declaration exactly. Yeah.
MR. KENNEDY: Yeah. Then I think that's the --
MR. CLEMENT: That's the cover page of 16.
BY MR. CLEMENT:
Q Okay. If you can turn to 3058248, towards the beginning. Do you have that page?
A I do.
Q Okay. And this was something you relied on, right, in your declaration?
A Yes.
Q And this is a -- this was attached to the Bays declaration; is that true?
A I believe so.
Q Yeah.
And what's on this page, 8248? Is that, like, the description of the study?
A Yes, it's the introduction methods and study design.
Q And that should be -- match up with the study in the patent?
MR. KENNEDY: Objection to form.

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THE WITNESS: It should be reasonably close certainly from the standpoint of lipid eligibility criteria --
BY MR. CLEMENT:
Q Okay.
A -- and medications that patients were taking.
Q Okay. You agree this was a double-blind study; right?
A Yes.
Q And the study in the patent is also described as double-blind; right? And feel free to take a look if you --
A I would --
Q -- need to.
A -- have to take --
Q It's not a --
A -- a look at that.
Q -- memory test, yeah.
A I don't remember how it's . . .
(Witness reviews document.)
I don't believe it says -- at least certainly not in the claim, I don't see where it says double-blind.
Q If you look at -- if you look at the

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example in column 13.
A Okay. So in the -- in the specification?
Q Yeah, in the specification.
A In the specification.
Q Yeah.
A Yes.
Q Okay. And how many arms were there on this study?
A I understand it to be two arms.
Q And what were --
A Oh, actually three arms. Sorry.
There was a placebo arm, an arm with Amarin at 2 grams a day and Amarin 101, 4 grams a day for a 12-week period.
Q And AMR101, we understand that to be a Vascepa?
A Amarin 101 is Amarin 101, yeah. That's -- that's Vascepa.
Q Vascepa, I keep saying Vascepa.
Okay. And it says that there's a matching placebo administered daily -- twice daily, right, in the --
A Yes.
Q And what does that mean?

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A Well, it means that if this was given one to one to one, then one out of every three patients would have been assigned to the Amarin 101, 4 grams a day, which is two capsules of active icosapent twice daily. Group two would have been assigned to Amarin 101, 2 grams a day, and group three would have been assigned to a placebo.
Q And the --
A Everybody getting two capsules twice a day.
Q Right.
And the capsules would all look identical from the outside?
A Capsules should look identical.
Q And what was the primary endpoint for the study?
A The primary endpoint was looking at the effects on lipids, so if we now turn to page -- page 8249, the next page, the primary endpoint, the change in triglycerides level from baseline to week 12, and then there were secondary endpoints as well.
Q Right. What were the secondary endpoints?

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A Secondary endpoints included changes in VLDL, ApoB and another marker known as Lp-PLA2.
Q And were the tests for statistical differences different from the primary and secondary variables?
A So I don't know the detail of how they determined statistics, but there were different significance levels assigned.
Again, as we spoke, it -- it's how the statistician determines, based on the power of the study, how many patients they need to enroll to get to those specified endpoints.
Q And for the primary efficacy variable -- strike that. For the primary endpoint, the significance level is .01; right?
A That's what it says.
Q And for the secondary variables, it was .05; right?
A That's what it says.
Q Now, do you know if this -- this test for the secondary endpoints was contained in the patent?
MR. KENNEDY: Objection to form.
THE WITNESS: Yeah, I -- I do not know.
BY MR. CLEMENT:

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Q Well, can you take a look? I think that the statistics -- at least the only part of the statistics I can find in the patent, I think that you cite to in your declaration, is column 16, lines 31 to 50.
A Right. That discusses the primary efficacy analysis, and then they also say they could use the same model for analysis of secondary efficacy variables.
Q But according to what we looked at under -- in the follow-up for the '727, they were different; right?
A Well, I actually don't know. I mean, I think this is under the auspices of the statistician who could tell you -- get into the weeds with you and go into the specific rational and why the patent might look a little different.
I just don't know.
Q Okay. But this -- you're sitting here, and you are the declarant and one of the terms we're talking about is "statistical significance."
And is there anything in this patent that says for the secondary endpoints you should use a significance level of p as .05?
MR. KENNEDY: Objection to form.

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THE WITNESS: Yeah, again, I'm not a statistician, so I don't know. And I was not involved in the MARINE trial, so --

BY MR. CLEMENT:

Q So sitting here today, you can't point to anything in the patent showing that the statistical significance level for the secondary endpoints should be .05; right?

MR. KENNEDY: Objection to form.

THE WITNESS: Actually, I don't know if that's true because I would need to go through in fine detail the prosecution history where that information may reside, and I could also go through the specification to --

BY MR. CLEMENT:

Q That's fair.

A -- see if it's there.

Q But I'd like you to look through the specification. I don't think we need to look through the prosecution history right now. I'd like you to look at the specification.

A (Witness reviews document.)

So with respect to the specification, I don't see -- I -- I can't answer your specific question, but that doesn't preclude the

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possibility that that information resides in the prosecution -- elsewhere in the prosecution history.

Q But it's not in the patent specification; right?

A I -- I do not see it.

Q And both change in --

A Oh, one second. Hold -- hold -- hold on one second. Sorry.

Your question related to .05 and .01; is that right?

Q Right.

A So .05 is under column 16 starting at line 31 where they said, The least square means, standard error and two-tailed 95 percent confidence interval for each treatment.

And then going to line 47 when they're talking about the sample size number needed to identify a difference with a significance level of -- as less than .01.

Q That's not .05; right?

A The statistical analysis in -- on page 8249 says, The primary efficacy analysis was performed using a Wilcoxon rank-sum test at a significance of 0.01. And if we look at line 45

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on, it says, Assuming a standard deviation of 45 percent TG measurements and a significance level of less than .01.

So those who are consistent.

Q Right. I agree. That's the primary variable. I'm asking about the secondary which is the LDL and the ApoB; right?

A I -- I don't see it in the '728. It doesn't rule out the possibility that it may exist in one of the other asserted patents.

Q Okay. But you don't see it here in the '728; right?

A I haven't -- I didn't see it when I just glanced over it.

Q Okay. What is the NCEP therapeutic lifestyles changes diet?

A So a therapeutic lifestyle diet is -- is really a diet that incorporates lower amount of -- of fat in the diet, usually a reduction in total unsaturated fat, maintaining macro nutrient composition in a manner that may be reflective for allowing a subject to reduce his or her weight.

I mean, they're general -- they're general recommendations.

Q I guess -- yeah. So what -- do you --

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do you have the NCEP -- third report of the NCEP panel there which would have been Miller 15?

A I have it right here.

Q Okay. If you turn to 290029, and I just want to know if that's kind of what you're talking about with regard to what the TLC would be?

A So 290029?

Q Yep.

A Essential components of a therapeutic lifestyle change, so the recommendation is to reduce saturated fat, reduce dietary cholesterol, adjust total caloric intake for -- either to maintain body weight or perhaps to lose some, physical activity.

Q Right. So what's described in Tables 1, 2 and 3 on that page, would that be your understanding of --

A So that would be -- so that's -- Table 1 is essential components, Table 2 is macronutrient recommendations and Table 3 is -- I'm not sure about Table 3. I mean, it's dietary guidelines for Americans.

Q Okay. So 1 and 2?

A One and 2 I think are --

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Q Okay.
A -- reasonable.
Q That's good. Okay.
Now, in the study protocol for the example in the patent, right, the '728 patent, remember the example?
A Yes.
Q When were the baseline triglyceride measurements taken?
A Yes, I -- I believe the blood levels, if I'm not mistaken, were taken after this four- to six-week washout period. And then there was an average. You could have one drawn after the four- to six-week period and then you could -- then you would repeat that, I believe, within a week or two; take the average of those two and -- then determine eligibility with the possibility that if that person's triglyceride was outside that range but in the ballpark, you may do a third one and then take the average of the third one and the second one. Typic- -- the typical way that clinical trials are conducted.
Q Okay. And once you got that number, that was your baseline; right?
A That would be -- that would determine

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actual eligibility to participate in the clinical trial.
Q And if you were eligible to participate in the clinical trial, that would represent the baseline for that subject?
A That would represent the baseline for that subject.
Q Okay. Now, it is true that subjects --
A For the -- for the purposes of the -- of the clinical trial.
Q Of the clinical trial?
A Of the clinical trial.
Q Right.
So the subject could then change his diet or no?
A No, the diet was recommended throughout the study --
Q But if they --
A -- as -- as is generally done.
Now, whether or not a patient veers off his or her diet is a different issue, but the idea is for patients to maintain that -- that lifestyle that they were moni- -- following.
Q But if they were to change their diet or exercise, either more or less, that could skew

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the results; right?
MR. KENNEDY: Objection to form.
THE WITNESS: Well, in any clinical trial if you go off your medications or you do things you're not -- you shouldn't be doing, then of course it could skew -- it might skew your results.
BY MR. CLEMENT:
Q Now, in the protocol were the subjects allowed to -- the subjects who -- strike that.
In -- in the protocol -- in the example in the patent, were subjects allowed -- if they were taking a statin, were they allowed to continue taking a statin?
A That was my recollection, is that they could be on a statin -- a percentage of those patients, maybe 25 percent, were taking a statin, and they could remain on a statin.
The only medications -- they could not remain on other medications, but they could remain on a statin -- they -- I mean, I think ezetimibe might have been permitted. But they couldn't remain on medication that might affect triglycerides.
Q That was one -- another one of my

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questions. I can't -- I don't remember if I remember clearly. Was ezetimibe allowed to be continued?
A I'll have to look. Let me -- Let me check.
Q Go ahead and take a look. Sure.
A Because I -- again, I was not a part of the study but if recollection serves me correctly, that was the case.
MR. KENNEDY: Do you need the patent?
THE WITNESS: No, I'm looking actually for the clinical trial.
MR. KENNEDY: Oh, I think it is one of the big -- big guys.
THE WITNESS: One of the big guys?
BY MR. CLEMENT:
Q I think it's in one of the file histories. If you want to look at that -- that document we were just looking at, it's in Miller 16.
MR. KENNEDY: The Bates --
THE WITNESS: Oh, there it is.
MR. KENNEDY: There you go.
THE WITNESS: Great. What page was that?

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BY MR. CLEMENT:
Q I think it's on --
A Okay. I got that.
Q -- 248.
Feel free to look it up, whatever you think you need to.
A (Witness reviews document.)
So inclusion -- let's see. If on backgrounds statin therapy no change to statin type or dose during the study was allowed.
With respect to ezetimibe, I would actually have to look at the paper because I don't see it here.
Q But statins, they were allowed to continue on; right?
A Yes, correct.
Q With icosapent and the statin, the statin would be considered concomitant lipid-altering therapy; right?
A Yes.
Q Does the patent say how many patients were on the statins?
A Again, I would have to look through the information presented both in specification and prosecution history.

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Q Well --
A My -- I -- I think I would -- I believe that it would be in prosecution history if it wasn't present in specification.
Q Okay. Maybe in the pros- -- I'm -- but my question is in the patent itself. I'm just asking in the patent itself.
Is there a recitation of what percentage of patient -- of subjects of the study were on a statin?
A I'll probably have to look through that.
Q And just so you know --
A And, again -- sorry. And this is specifically '728.
Q Yeah.
A (Witness reviews document.)
I -- I do not see reference to --
Q I -- I didn't --
A -- the percentage --
Q -- see it either.
A -- of patients.
Q Yeah.
Also I did just notice -- just maybe it solves our mystery a little bit, but if you look

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at the column of 13 about line 63, it says, If statin therapy (with or without ezetimibe) is to be continued, dose must be stable for four weeks.
Does that mean if they were already on ezetimibe in addition to the statin, they were allowed to continue?
A Yes, that -- that -- that was my understanding.
Q Okay. And ezetimibe is not a statin; right?
A That is correct.
Q But it is -- when taken in combination with icosapent and a statin, ezetimibe would also be considered a concomitant lipid-altering therapy?
A Yes.
Q Is there any statistical-significance testing for subjects who are on statin therapy versus -- as opposed to subjects who are not? They didn't break that out; right?
MR. KENNEDY: Objection to form.
BY MR. CLEMENT:
Q Do you follow my question, or am I --
A I understand --
Q -- being unclear?

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A -- your question.
I -- I -- again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better reduction in triglycerides than those who were on icosapent in the absence of statin.
Q Okay. But do you know if there was a difference in the statistical-significance testing for those -- for those two different types of subjects?
A We'd have to look through it.
Q It's not mentioned in patent; right?
A I don't recall.
Q Okay. Let's take a look at paragraph 40 of your opening declaration which is Miller 2.
Okay. At the end of that paragraph -- and feel free to read the entire paragraph, but you say, The clinical trial demonstrated that the invented method has numerous, unexpected and beneficial effects on lipid profiles in patients with very high triglyceride levels receiving diet and lifestyle-change counseling; right?
A Yes.

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Q So would you -- I guess, did you base that on the claim of the patent?
MR. KENNEDY: Objection to form.
BY MR. CLEMENT:
Q What the invented method was?
MR. KENNEDY: Objection to form.
THE WITNESS: I based that on the totality of the infor- -- information that I had available to me.
BY MR. CLEMENT:
Q Okay. And this invented method, right, that was -- included giving -- administering the 4 grams of purified icosapent?
A Yes.
Q Did they take -- did the patients or the subjects take anything else?
MR. KENNEDY: Objection to form.
THE WITNESS: Well, if they may have also been taking their statin therapy and/or ezetimibe.
BY MR. CLEMENT:
Q Okay. And then their lipid parameters, right, those -- that were talking about triglycerides -- talking about triglycerides and ApoB for purposes of -- and LDL-C --

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A Yes.
Q -- okay. Those were measured; right?
A Measured or calculated, correct.
Q Okay. And those lipid levels, right, that the -- were measured or calculated from the patient -- from the subject's bloods, those were the natural result of a patient ingesting the medication?
MR. KENNEDY: Objection to form; outside the scope.
THE WITNESS: Yeah, I -- I think it was basically a by-product of having the physician recommending that the patient take the medication, telling the patient what time he or she should take the medication, and then ultimately as part of this process the patient taking the medication.
MR. KENNEDY: By -- by the way just so -- so the record's clear, I think you've developed a habit of saying yeah before a lot of your answers. I don't know if that's intended or not, but in context sometimes yeah doesn't make any sense.
THE WITNESS: Okay.
MR. KENNEDY: So if you could just be precise, and --

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MR. CLEMENT: Yeah, that's fair, but let's stop coaching the witness, too.
MR. KENNEDY: Okay.
BY MR. CLEMENT:
Q So, again, it's really -- what happens -- the lipid levels, right, that -- that are developed in the patient's bloodstream; right? Because that's what they do, they take the blood, and then they run it through some sort of assay or some analysis. And they can measure for triglycerides, let's say, milligrams per deciliter; right?
A Yes.
Q That -- those numbers that come out of the blood or -- or get -- when they're analyzed, that's because of just when the patient ingests the product, the body just metabolizes it however the body metabolizes it; right?
MR. KENNEDY: Objection to form.
THE WITNESS: Well, it's a little bit -- that -- it's more than -- that's an oversimplification.
So after the instruction -- instructions are given with regard to administration and the patient takes the

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medication, then that medication is absorbed and catabolized to some degree, and there are different kinetic parameters involved in the bioavailability of the medication.
BY MR. CLEMENT:
Q That's all natural processes occurring withinside the body. That's how the body acts on the medication.
MR. KENNEDY: Objection to form.
THE WITNESS: That's how ultimately it gets processed.
BY MR. CLEMENT:
Q Yeah.
And that would include for the ApoB levels, the LDL-C levels and the triglyceride levels; right?
MR. KENNEDY: Objection to form.
THE WITNESS: For all those blood levels that were being evaluated, they would be -- blood sampling would be taken after a period of time that the patient had been exposed to either the active compound or the inactive compound.
BY MR. CLEMENT:
Q And that -- you know, there would be a protocol for that; right? What time do you draw

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the blood; right? There's all sorts of protocols that have to be taken within plus or minus five minutes of certain times, right, spelled out in the protocol?

A I think that might be a little specific. I'm not sure that a patient had to have his or her blood drawn at a specified time period.

Q Uh-huh.

A It's usually when a patient comes in for his or her follow-up visit, that designated time. There -- there is a window when you would want that patient to come back, and that's specified in the protocol.

Q Okay. And, again, the -- the resulting ApoB levels in the blood is just from the patient, you know, taking the medication as prescribed, and it's just what comes out of the blood at that -- after that point; right? There's nothing -- no intervening act after the patient ingests the medication other than natural processes in the body that give you that ApoB level or that LDL-C level; right?

MR. KENNEDY: Objection to form.

THE WITNESS: Yeah, I'm not -- I'm not quite sure if -- if it's as simple as that because

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it's not as if you're taking or drinking a milkshake and then determining the number of chylomicrons. So to see effects on a given parameter, it doesn't happen instantaneously. And to see lipid effects, we're looking at a period of time where those changes are observed, so --

BY MR. CLEMENT:

Q And I'm not suggesting it happens instantaneously. I agree with you. It takes time. But everything that time is is things that the body is naturally doing in its course of absorption, metabolism, distribution and elimination; right?

A But, again, I want to point out that the process of administration is a broad term. It's not limited to somebody putting a pill in his or her mouth and then monitoring the blood levels.

Q Right. I'm not going there.

I'm just saying after they take the pill -- I'm not using the word "administering" at all. Okay.

After the person takes the pill when you then later at some point in time take the blood sample, okay, to measure their ApoB levels or LDL-Cs according to whatever the protocol is,

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that's all natural processes; right?

MR. KENNEDY: Objection to form.

THE WITNESS: May or may not be natural because, again, we'd like to believe that it's natural, but there could be some other --

BY MR. CLEMENT:

Q But --

A -- you know, intervening circumstance.

Q But you would agree it's all how the body is acting on the drug after it's been ingested; right?

A For the most part.

Q Yeah.

Well, what part wouldn't be?

A Well, you know, how one person responds to a medication could be different than another person.

Q Right. But that would be by their own inherent body makeup; right?

A It's just -- I -- I think with -- when we view metabolism, it's -- it's a little bit more complex, but I think the point you're suggesting is -- is -- is fairly reasonable.

Q Okay. Okay. What does the word "concurrent" mean?

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A Concurrent is usually with -- with something else.

Q And what about "concomitant"?

A I view them very similarly.

Q Okay. They're kind of synonymous; right?

A I think so.

Q Will exercise alter lipid levels?

MR. KENNEDY: Objection to form.

THE WITNESS: Exercise might have an effect on lipids as it would on blood pressure and weight and glucose. So, yes, exercise is another broad-based measure that could -- that could affect a lot of things.

BY MR. CLEMENT:

Q And diet can also alter lipid levels; right?

A As it could blood pressure and weight and glucose and so forth.

Q All right. But lipid levels included; right?

A It could affect lipids. It's not a lipid-lowering therapy, but it can affect lipids.

Q Okay. If you turn to paragraph 53 in your declaration. And here you're talking about

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concomitant and concurrent lipid-altering therapy; right?
A Yes.
Q And you say they're understood in the field to refer to other medications that a patient may be taking that will overlap with a prescribed course of treatment; right?
A Yes.
Q What do you mean by "overlap"?
A Well, as I've stated earlier, lifestyle therapy or -- or therapeutic lifestyle change as it is often referred to really is an initial recommendation for all patients that are presenting with any level of cardiovascular risk.
So in this particular case here for patients that have -- or may need to be treated because of an abnormal lipid or an abnormal blood pressure or abnormal glucose, then we would make recommendations for lifestyle therapy.
Q And then on paragraph 55 of your declaration, where you rely on -- you talk, again, more about concomitant and concurrent lipid-altering therapies; right?
A Yes.
Q And you rely on the patent, right,

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here, column 12, lines 43 to 46 of the '728?
A I believe that's in the specification.
Q Okay. And if you turn to that, I mean, would you consider that to be -- I mean, we talked earlier about definitions, right, that a specification gives; right?
A Yes.
Q Is this definitional, do you think?
MR. KENNEDY: Objection to form.
THE WITNESS: Well, from the standpoint of this particular patent, it appears to be medication. Lipid-altering therapy, I would -- I would view as lipid-altering medication given the examples of statin, fibrate, niacin and/or ezetimibe all of which are medications.
BY MR. CLEMENT:
Q Okay. But this is not defining -- do -- do you think this is defining the term "lipid-altering therapy" -- I'm sorry. Strike that.
Do you think this portion of the '728 patent, column 12, lines 43 to 46, is defining the term "concomitant lipid-altering therapy"?
A I'm not sure this specific one is, but there are others that I refer to in my

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declaration.
Q So -- so you're relying on this portion just to support your understanding of the term, not necessarily as a definition; right?
A Correct.
Q Okay. Because "embodiment," that just means it's giving an example; right?
A Yes.
Q And even when it lists the medicaments, right, it says, For example; correct?
A I'm sorry. Where are you?
Q So where it says, Statin, fibrate, niacin and/or ezetimibe therapy. Do you see that?
A Yes.
Q It's prefaced by that. The language is prefaced by "for example"; right? Do you see that?
A Right. They could have included bile acid sequestrants as well, and they didn't.
Q They could have included a lot of things. They just gave examples; right?
A Well, no, this is medicine. This is clear as day to me that this refers specifically to medication. These are all medicines. I have no reason to believe that it is anything

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otherwise.
Q Understood.
But they're just giving examples; rights?
A Yes.
Q And statin -- some of the people in the example were on statins; right?
A As part of this clinical trial, the MARINE clinical trial, yes.
Q So if someone is on statins at the same time they're on the icosapent and the claim says not otherwise on lipid-altering therapies, they're outside the scope of that; right?
MR. KENNEDY: Objection to form.
THE WITNESS: All right. Could you point to me where that is --
BY MR. CLEMENT:
Q Look at --
A -- specifically --
Q -- claim 1 --
A -- said.
Q -- and it says, A method of reducing triglycerides in a subject having a fasting baseline triglyceride level of 500 mgs to dl to about 1500 mgs per dl who does not receive

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concomitant lipid-altering therapy; right?
So if they're on a statin, they're not included on that claim, right, because they're on a concomitant lipid-altering therapy under your definition; right?
A Yes, so my -- my -- my understanding of concomitant lipid-altering therapy are those individuals who may have been receiving niacin, fibrates or other triglyceride-lowering medications.
Q So --
A That was -- that was my understanding.
Q But the patent says otherwise. It says, For example, statins and ezetimibe; right?
A Statins and ezetimibe were permitted as part of the MARINE trial.
Q Are they permitted as part of this claim if it says they do not receive concurrent lipid-altering therapy?
MR. KENNEDY: Objection to form.
THE WITNESS: Well, I think it would have to be linked to the prosecution history where in the prosecution history it does establish that the MARINE trial consisted of patients who received eicosapentaenoic and may also have

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received statin --
BY MR. CLEMENT:
Q Is it possible --
A -- or ezetimibe.
Q -- the MARINE -- is it possible the MARINE trial -- the patients on that -- the statins and the ezetimibe in the MARINE trial just aren't included in this claim?
MR. KENNEDY: Objection to form.
THE WITNESS: Oh, I -- I -- I -- I wouldn't interpret it that way.
BY MR. CLEMENT:
Q Well, you've agreed with me before, right, that statins are a concomitant lipid-altering therapy; right?
A They are a concomitant lipid-altering therapy, but they are not a specific agent to lower triglycerides.
And this specific claim is to have patients who have elevated -- very high triglycerides of at least 500 and statins would not be thought of as a triglyceride-lowering therapy as you would think of niacin and fibrates and so forth.
Q So let me get -- understand this. So

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it's your position, it's your opinion that statins although when taken with icosapent in general are a concomitant lipid-altering therapy.
When you look at it in the context of this claim, it's not? Is that what you're telling me?
A I'm not saying it's not. But what -- what I'm saying is when I'm looking at concurrent lipid-lowering medications, I'm thinking more in terms of the specific triglyceride-lowering medications.
Q The patent says in the section you pointed to, column 3, lines 43 -- column 12, lines 43 to 46, all right, not otherwise -- that in accordance with the methods of the invention, not otherwise on lipid-altering therapy, for example -- the first one is statin.
Now you're telling me that doesn't count? Is that your testimony?
A Well, statins count. What I'm specifically referring to are triglyceride-lowering medications.
Q Well --
A Statins -- statins count. I think -- what my understanding here is lipid --

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lipid-altering therapy or medications that lower lipids -- medications that lower lipids, and that -- and that is how --
Q Well, statins lower lipids; right?
A Yes, the --
Q Okay.
A -- primary treatment for the use of statins is to lower LDL.
Q Which is a lipid?
A Yes.
Q And they're talking here -- they don't say in the claim triglyceride-lowering concomitant therapies, they say concomitant lipid-altering therapy which would include LDL?
A But I think they -- the point here is that the focus is on the hyper -- the very high triglyceride patient, VHTG baseline triglyceride of at least 500. And, so, when you're thinking of patients in the -- in the trial -- in the MARINE study with a fasting baseline triglyceride of 500, they excluded or washed out patients that were receiving other triglyceride-lowering medications.
So there is a distinction between a triglyceride-lowering medication and another agent such as --

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Q A lipid-altering therapy; right? Triglyceride --
A No, the L- -- the primary LDL-lowering --
Q All right.
A -- therapy.
Q But an LD- -- so would you -- would you agree with me, if I'm looking at a venn diagram, lipid-altering therapy could be drugs that treat any lipid and triglyceride-lowering therapies would be just within that -- a circle within that that treat -- that lower triglycerides; right?
A You're looking at VHTG, so it's a special group of patients.
Q And --
A Very high triglycerides.
Q 25 percent of them in the patent met -- for example, I think you said were also on statins --
A Yes.
Q -- and/or ezetimibe.
A I'm not --
Q Right?
A I'm not saying that -- I'm not discounting statins.

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Q Okay.
A I'm just saying my -- my reading is -- in terms of the MARINE study was to exclude patients that were not on triglyceride-lowering medications because of the population being studied.
Q Okay. But I'm asking about lipid-altering. Are you telling me now, sitting here today, that when the patent claim here says concurrent lipid-altering therapy that should be read to say concurrent triglyceride --
A No.
Q -- altering therapy?
A Of course not. I mean, it could be any lipid-lowering medication.
Q Such as a statin?
A Of course.
Q So if someone is on a statin at the same time they're on the icosapent, they're on a concurrent lipid-altering therapy; right?
A Yes.
Q And then it -- since this says who does not receive concurrent lipid-altering therapy, they would not be in the -- within the claim; right?

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A Well, again, I want to be careful because obviously in the MARINE study statins were permitted to be used.
Q I'm not asking in the MARINE -- I'm asking about the claim.
A 500 to 1500, the focus is on triglyceride-lowering medications.
Q And patients on five -- who have over 500 milligrams per deciliter of triglycerides, are also sometimes on statins; right?
A Yes.
Q Okay. So there are patients who have -- who are on this -- above the five -- between the 500 and the 15 who are also on a statin. And my question is when we give them the icosapent, does that mean that they are receiving concurrent lipid-altering therapy?
MR. KENNEDY: Objection to form.
THE WITNESS: If they are receiving a combination of eico- -- eicosapentaenoic and another cholesterol or lipid-lowering medication.
BY MR. CLEMENT:
Q And, so, then they can't be considered someone who is not receiving a concurrent lipid-altering therapy; correct?

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A Again, with -- with respect to the clinical trial, patients in the clinical trial with triglyceride levels between 5- to 1500 could not be taking or had to be washed out of a triglyceride-lowering medication. They did not have -- they did not have to be washed out of a statin.
Q I understand that. But I'm asking within the scope of a claim, and I think we agreed a person who is taking -- who has 500 to 1500 mgs per dl of triglycerides, that is taking icosapent and is also taking a statin, they are on a concurrent lipid-altering therapy; right?
A Yes.
Q And I'm just looking at the claim. I'm not looking at the study. I want to just keep this focused on the claim.
Within the scope of that claim if it says they are not receiving concurrent lipid-altering therapy, they can't also be -- that would exclude people who have both icosapent and a statin; right?
A (Witness reviews document.)
Within -- within this interpretation of what -- of what you said, that would be -- that

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would be the case.
Q Okay. You also talked about Katayama; right?
A Correct.
Q In your declaration.
Let's turn to Katayama which, I guess, is in the '728 file wrapper.
Did I mark that one? I don't know if I marked that one yet.
MR. KENNEDY: I don't think so.
MR. CLEMENT: Let's skip that for now. I'll find it at the break.
BY MR. CLEMENT:
Q All right. Can a patient administer a medication to his or herself?
A Yes.
Q And that's by taking the medication?
A Yes.
Q So, I guess, one of the questions I'm having and I'm not even sure this is a dispute between plaintiff and defendants on the term "administering". My view of it is that administering can include the doctor prescribing. It can include all those steps before, but that it has to include the patient actually ingesting the

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medication.
Is that your understanding?
A No.
Q No, okay.
Tell me where I'm wrong.
A I write a prescription for a patient. I advise the patient to take the medication at X time. Patient goes on his or her way. I don't -- I don't know what happened. But as far as I'm concerned, I administered the medication.
Q So just by writing that script and talking to the patient, that's administering?
A That is -- that is administering. I'm not going to be there to see -- to watch every time the patient takes the medication. I -- I presume that to be the case, but administering encom- -- is, again, another broad term that encompasses one of several different avenues, if you will.
Q Okay. So maybe we do have a dispute on this.
Okay. And if you prescribe it, you're saying you don't know if the patient takes the medication; right?
A Well, I presume the patient is taking

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it.
Q But patient compliance is an age old problem, right, between doctor and patients?
A Well, it's not so much between doctors and patients. It's usually -- we try to do our job.
Q Right.
And the patients --
A You can bring --
Q -- don't always do theirs?
A You can bring the horse to water.
Q Right. Okay.
But patient compliance is an issue when you're trying to treat a patient; right?
A It can be.
Q It can be. Okay.
So patients -- while you would like them to always take the drug, they don't always?
A Yes.
Q And they don't always take it as prescribed maybe?
A Correct.
Q But you do agree that administering could include the patient actually taking the medication?

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A Yes.
Q So they can self-administer?
A Yes.
Q Which has nothing to do with writing a prescription; right? They're just taking the pill then?
A That's part --
MR. KENNEDY: Objection to form.
THE WITNESS: That's part of the process. They -- they can't take the pill if I haven't prescribed it.
BY MR. CLEMENT:
Q Well, what if they just go -- an off-the-shelf medication, can they administer an off-the-shelf medication to themselves, omega-3, whatever, fatty acids that are off the shelf?
A They can do that without my knowledge.
Q That would still be administering?
A Not a for -- not -- not -- not a -- a prescription form. Prescription form has to be written with directions provided by the health care professional.
Q Okay. Do you know if the term "oral administration" is defined in the patent? All right. Some of the claim term -- claims use oral

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administration; right?
A Yeah, I believe it was.
Q And that's at column 12, line 49?
A Yes.
Q And they're defining oral administration, right, in that -- in that paragraph?
A They are.
Q Is there anything about a prescription being written in that paragraph?
MR. KENNEDY: Objection to form.
THE WITNESS: I believe that information is presented elsewhere in the intrinsic evidence.
BY MR. CLEMENT:
Q Okay. But it's not in that paragraph; right?
A Not in this specific paragraph.
Q But what is in that paragraph is the patient actually putting it in their mouth; right?
A In this particular paragraph, that's the case. But elsewhere, there are other examples within the intrinsic evidence demonstrating that administration includes the action by a physician.
Q But here they're defining oral

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administration; right?
A Within this one paragraph.
Q Okay.
MR. CLEMENT: Why don't we -- have we been going an hour.
MR. KENNEDY: Yeah. Yeah.
MR. CLEMENT: Let's take a break.
THE VIDEOGRAPHER: The time is 2:16 p.m. We are going off the record. This concludes tape number 4.
(Recess -- 2:16 p.m.)
(After recess -- 2:36 p.m.)
THE VIDEOGRAPHER: The time is 2:36 p.m. This begins tape number 5. Going on the record.
Please proceed, Counsel.
BY MR. CLEMENT:
Q Okay. Dr. Miller, if you turn to paragraph 79 in your report, and there you're talking about the definiteness; right?
A Yes.
Q And you say that defendants -- you said you understand that defendants must prove by clear and convincing evidence that a claim is indefinite; right?

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A Yes.
Q What does "clear and convincing evidence" mean to you?
A I -- I would say clear and convincing evidence is -- is -- it's the usual term.
Q What does that mean, "usual term"? What does it mean to you?
A That it doesn't exist. That there's evidence to -- to -- to otherwise refute.
Q So it's your understanding there's no other -- in order to meet the clear and convincing evidence standard, there has to be no evidence otherwise to refute?
A To refute it, to refute what is viewed as -- as -- as it's been written.
Q Okay. What is your understanding of what "indefiniteness" means in the context of your declaration?
And feel free to glance through.
A Yeah, I mean, as I say in paragraph 79, Fails to inform a person of ordinary skill in the art about the scope of invention with reasonable certainty.
Q In general are statistically significant changes always clinical meaning --

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clinically meaningful?
A No.
Q Would you agree that it's your opinion that a -- and I'm looking at paragraph 81 -- that a substantial increase in lipid levels is one that would affect how a clinician would respond to such an increase?
A Yes.
Q And is that different for different patients?
A Could be.
Q So for a different increase in lipid levels depending on how else the patient presents, you might treat them differently?
A Depends on the -- the lipid you're looking at and evaluating.
Q What about for -- if you're looking at triglycerides?
A Yeah. You know, as we've said, the patients that have very high triglycerides are viewed differently than patients who have very normal triglycerides.
Q Do you view all your patients who have very high triglyceride levels, above the 500 mgs per dl, similarly or do you treat them as they --

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individually as they come and might treat them differently depending how they present?

A I was --

MR. KENNEDY: Objection to form.

THE WITNESS: I -- I treat patients based on -- I treat them individually.

BY MR. CLEMENT:

Q Based on their overall health and all their levels of different --

A Yes.

Q -- markers; yeah?

Can you say without seeing a patient whether a 5 percent rise in LDL-C is clinically meaningful?

MR. KENNEDY: Objection to form; incomplete hypothetical.

THE WITNESS: Right. So as a -- and this is -- your question is outside the scope of the patent; is that correct?

BY MR. CLEMENT:

Q Yeah.

A Yeah, so if a patient -- you know, as a clinician, that -- that is viewed as a threshold, that a 5 percent change -- and in this particular case we're talking about approximate 5 percent

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increase in LDL. Was that what you were referring to?

Q A 5 percent rise, yes --

A A 5 --

Q -- increase.

A -- percent rise in incr- -- in LDL would be viewed as kind of the threshold where -- where I or another POSA might consider making dose adjustments.

Q What if -- so 10 percent or 15 percent, that would -- you would also consider that clinical --

A Yeah, I think about 5 percent give or take the threshold above which we would make changes, or we'd certainly consider making changes.

Q But you would want to know more about the patient before you decided whether or not to make changes; right?

A We'd always want to know more about the patient.

Q Is a 5 percent rise in an LDL-C level -- is that -- for patients with over 500 mgs per dl, is a 5 percent rise in an LDL-C level a treatment challenge?

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MR. KENNEDY: Objection to form.

THE WITNESS: Right. So remember in a patient for whom triglyceride levels are in a very high range, above 500, our -- our first and foremost goal is to try to lower triglycerides.

Once we get it below 500, give or take, then we move from the concern of pancreatitis risk to the concern of coronary risk.

BY MR. CLEMENT:

Q And when you were talking about that 5 percent -- when we were talking about the 5 percent number just a few minutes ago, was that based on your rule of six?

A Yeah, 5 to 6 percent is in part based on the rule of six.

Q In the rule of six, did you mention that in the -- your opening declaration?

A I believe I may have mentioned it in my response, my second --

Q Right. I'm asking about your opening.

A I'm not sure if it was mentioned in the opening, but I believe it was mentioned in the second.

Q Okay. I agree with you it was mentioned in the second, but, again, you didn't

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mention it in the first; right?

A I -- I would have to go through that again. I know it was mentioned in the second.

Q So in paragraph 81 of your opening report -- declaration, you talk about a substantial increase in lipid levels being one that would alter how a physician would view the patient's risk of developing a disease and would necessitate consideration of a new treatment or change to existing treatment; right?

A Yes.

Q So as a physician, would you consider an increase of LDL-C from 90 to 100 significant?

A Well, I think -- again, this is hypothetical, and I think you would need to look at the patient's overall risk and what other risk factors may be evident.

Q How about a 100 to 106 rise in LDL?

A So, again, as I just mentioned before, this is hypothetical, and a 100 to 106 is an approximate 6 percent increase in LDL if my math serves me correctly. Again, that is the -- that is a little bit -- right around the threshold where you need to at least consider that.

Q But you'd want to see the patient;

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right?
A I don't play telemedicine.
Q Okay. So let's look at paragraph 83 of your declaration, and you're saying, Doctor -- you say, The applicants submitted a declaration from Dr. Bays reporting a 4-gram per day dose of AMR101 reduced triglycerides over 35 percent without a significant change in LDL-C.
Do you see that?
A Yes.
Q So what was that significant change; do you know -- or without a significant change?
And I think you have the '727 file wrapper there with you if you need to look at that and --
A Yeah, why don't I -- don't I take a look at that.
(Witness reviews document.)
So for LDL cholesterol, the difference between the Amarin 4 grams a day versus placebo was approximately 2 percent --
Q Okay. Which --
A -- and 3 percent.
Q Which page are you looking at?
A I'm looking at page 8246.

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Q 8246.
And what numbers are you looking at?
A I'm looking at Amarin 4 grams a day versus placebo, and this is baseline -- percent change from baseline in the MARINE study.
Q And that was a 2.3 --
A Correct.
Q Negative 2.3; right?
A Negative 2.3.
Q So that's not five or six; right?
A That is not five or six.
Q And you also look at the Weintraub -- or, no, I'm sorry.
In the '727 file wrapper, you also -- and Dr. Bays was talking about significant change and not substantial; is that correct?
MR. KENNEDY: Objection to form.
THE WITNESS: Let me see the specific wording that he used. I'd have to look to see exactly. Let's see.
(Reviews document.)
Right. He says significant change.
BY MR. CLEMENT:
Q So that doesn't really support your substantial change being five or six, right,

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that -- that -- that citation to that?
MR. KENNEDY: Objection to form.
THE WITNESS: I was referring more to what would be viewed as a clinically meaningful change, so --
BY MR. CLEMENT:
Q Right. But this is a paragraph you put in your declaration in this section, and I -- I thought it was -- what was the purpose of putting it in there if it wasn't to support what a substantial change is? It's under the substantially -- "without substantially increasing" claim term; right?
MR. KENNEDY: Objection to form.
THE WITNESS: Let me see if that's actually -- I'm -- I'm looking at a -- on a different page. Let me see if I can find that specific page.
(Reviews document.)
So now I'm looking at on page 20 which is actually 0317 Bates number 9808 where he mentions this with respect to reduction in ApoB and substantially no increase in LDL as well as the satisfaction of a long felt, unmet medical need.

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BY MR. CLEMENT:
Q Okay. Where is that again? You're on page 9- 9808?
A I'm on page 9808.
Q Where are you reading from?
A I'm reading from the second paragraph.
Q The one that begins -- which one? Beginning, Even if a prima facie case or --
A Yes.
Q Okay. Is this a -- the Bays declaration?
A Well, this is in the prosecution history, and it may be -- let's see. It may be from one of the examiners, but it does refer to Bays.
Q Where does it refer to Bays?
A Well, if you go to the previous page, it talks about Bays Declaration III.
Q Okay. But, again, my question is -- was there something -- you cited to -- I was looking at your declaration, paragraph 80 -- no, wait -- I'm sorry -- paragraph 83. And I'm just trying to get an understanding of why you cited to paragraph -- the Bays pages 3058235 to 36.
Does that or does that not support your

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argument that substantial change means 5, 6 percent?
A Yeah, I mean Bays says with -- with an LDL rise may necessitate the initiation of lipid-altering drug therapy.
Q But where does he say what that -- what rise? Is it any rise? Is it 5 to -- where does it say 5 or 6 percent?
A (Witness reviews document.)
Yeah, the 5 to 6 percent is -- is mentioned in other parts of the prosecution history. I'll find those for you.
Q No, that's fine. I'm just wondering -- is it mentioned in the -- in the -- and we can go there after.
I just want to know, for the record, is there anything in the Bays declaration that you cite to in page 83 of your report that supports your 5 to 6 percent number for substantial change?
A I think there is, but I would actually have to go through the entire document.
Q Sitting here today -- sitting here today, you can't do that? I mean, you cited --
A I can do that.
Q Okay. You --

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A I can --
Q -- cited --
A -- do that sitting here today, but it's going to take sometime.
Q All right. Why don't you take, you know, five or ten minutes and see if you can do that.
A Okay.
(Witness reviews document.)
I know Dr. Weintraub says it.
Q Okay.
A So I will find where Dr. Bays says it.
(Witness continues reviewing document.)
Q May -- I see you flipping through there. Are you looking at the Bays declaration --
A I'm looking --
Q -- or the --
A I'm looking at the Bays declaration right here, specifically right here.
(Witness continues reviewing document.)
Yes, he -- he talks primarily about the increases in LDL-C with other therapies, and not -- he doesn't specifically talk about 5 to 6 percent, but -- but Weintraub does.
Q Okay. So let's stick with Bays. Bays doesn't talk about 5 to 6 percent; right?
A He does not talk about 5 --
Q Okay.
A -- to 6 percent.
Q But you say -- but you say Weintraub does; right?
A That was -- that was my recollection.
Q Do you want to show me where?
A (Witness reviews document.)
Yeah, it's like he says -- and I say this on -- on number 85, Dr. Weintraub explained in a declaration submitted to the patent office: Even a small increase in LDL caused by triglyceride-lowering drug can have serious complications for patient. For example, an increase in concentration of LDL by about 6 percent can result in a need to double the concentration of a statin.
To mitigate this increase in LDL. This can result in an increase in cost for the therapy and a significantly higher risk of statin-related adverse events.
And then subsequent to that in 86 -- mentioned that typically an increase in LDL of about 5 to 6 percent in a hyperlipidemic patient

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would cause a physician to consider additional LDL-lowering treatment. The ATP guidelines explain that to decrease LDL by 6 percent double the dose of his statin.
Q Let's go one at a time. Okay?
A Sure.
Q So you're relying on this paragraph at the top of page 38 for your basis saying that Weintraub supports your 6 percent is a substantial increase; correct?
A It's substantial enough to consider a medication.
Q Okay. Is the word "substantial" in that paragraph?
A No, he uses --
Q He uses small increase; right? He doesn't even say substantial. He says, Small increase; right?
A Right. Because what he's -- what he's basing it on is the relative differences between what was observed in -- in the clinical trials inasmuch as -- in some cases the increase is a lot higher.
Q He says -- he's saying, Even a small increase.

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A Yeah.
Q He never says substantial. He says, Small?
A Yeah. Correct.
Q So he doesn't say 6 percent is substantial. He says that might be a small increase; right?
A Right. I believe I said substantial.
Q You said substantial. Exactly.
Let's look at what else you cite. You go on and in that same paragraph 85 you have another citation to the request for continued examination; right?
A Yes.
Q Okay. And that's at AMRN3059047, but first can you turn to AMRN3059035.
Do you see that's -- I'm sorry. Let me know when you get there. That's a request for continued examination.
Do you see that?
A Request for continued examination, yes.
Q Do you know what that is?
A It sounds like what is stated.
Q Okay. Do you have any other knowledge as to what one of those -- what a request for

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continued exam -- is that something the examiner says?
A I'm -- I'm not a patent attorney, so I'm just taking it for what it says.
Q Okay. And your page -- your citation to page 9047 is within this request for continued examination document that you're not 100 percent sure of what it is; right?
A Well, I'm -- I'm -- I'm presuming it's related to the unexpected results of Amarin 101.
Q Well, there's a section on that; right, on page 047 of that document? The whole document is not related to the unexpected results; right?
A Right, but . . .
(Witness reviews document.)
So I am presuming that this is related to claims that -- for the patent.
Q Okay. Now, what do you -- you rely on this -- I guess, this 4.5 number on the table the 9047; is that what you're --
A Correct.
Q And there's a footnote with regard to that; right?
A There is a footnote.
Q And that's for Lovaza data not for

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Amarin -- AMR101; correct?
A That is correct.
Q And it says, Lovaza data in borderline high/high triglycerides.
So does that even rate -- relate to very high triglycerides?
A No, but that may be where the small increase comes from because when you look at the 4.5 percent compared to results with Lovaza 4 grams a day in patients with very high triglycerides, you -- there was a 44.5 percent increase in LDL. So it's -- the 4.5 percent is -- is smaller compared to the 44.5 --
Q Understood.
A -- percent.
Q But your -- is the 4 -- are you -- I guess, let me ask this question. Are you relying on this 4.5 percent number for your -- the basis for your understanding that without substantial increase in LDL-C -- is a substantial -- you know, that it would be understood to be 6 percent by a person of ordinary skill in the art?
MR. KENNEDY: Objection to form.
THE WITNESS: Yeah, you know, I'm putting -- I'm trying to put this into context.

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And -- and as you see in paragraph 85, I specifically say that this was reported in patients -- the 4.5 percent LDL increase was reported in patients in the borderline high-TG to high-TG patient population.
BY MR. CLEMENT:
Q Okay.
A So that is -- that's the context by -- by which I put that.
Q Okay. So is that supporting your 5 to 6 percent number for substantial increase, or is it just nice information to know?
A I think it's all additional information. I think where -- the information is based upon a number of different areas that include the intrinsic evidence, so it's prosecution history, specification.
And, so, this is all part of the prosecution history.
Q Understood.
But does that support your -- determine -- this 4.5 percent number, are you using that to say that that's the 5 to 6 percent -- as a person of ordinary skill in the art would understand that a 5 to 6 percent change

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in patients with very high triglycerides -- would know that's what substantial change means?

MR. KENNEDY: Objection to form.

THE WITNESS: I think that 4.5 percent increase -- despite the fact that it's in a borderline high TG to TG patient population, a person of ordinary skill in the art would -- would see that, would notice that.

BY MR. CLEMENT:

Q Would notice that.

Would they -- would they assume that supports your 5 or 6 percent number for what a substantial change is in the very high triglyceride?

A Well, obviously this was not done in a very high triglyceride, and I pointed that out. It's in paragraph 85. I specifically say it's borderline high to high TG.

Q Okay. And it doesn't say anywhere in here that there's substantial, but that means substantial; right? I'm looking on what's on this page 9047.

A Yeah, I'm not sure if -- if that specific term was used. It doesn't detract from the fact that I think that substantial is

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clinically meaningful.

Q And do you see that in the footnote 2 on that page?

A Which page?

Q The same page we were looking at, 9047.

Do you see the footnotes at the bottom referring to the table?

A The statistical reviews noted that the significance of the small increase requires clinical judgment.

Q All right. This says a small increase there or not? Sub- -- substantial increase; right?

A Right because it is a small increase relative to the 44.5 percent --

Q Okay.

A -- noted below that.

Q But they said it's was a small increase, not a substantial increase; correct?

A Correct.

Q Okay. What about the 8.4 percent number on the Epadel, right? Do you see that?

A Correct.

Q So even though that's a larger number than the 4.5, the footnote for that says it wasn't

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statis- -- statistical significant; right?

A I see that.

Q And you're not relying on that entry for support of what "substantial change" means; correct?

A Correct.

Q And you know in footnote 2 they talk about this Lovaza approval package.

Do you see that?

A I see that sentence.

Q Have you ever seen the Lovaza approval package?

A I believe I have.

Q Did you look at it in context for preparing your declarations in these case -- in this case?

A If it's within this prosecution history, then I did.

Q No, I don't think it is.

A Then I may not have.

Q You also rely on a Baigent article; is that right?

A Baigent.

Q Baigent.

A Yes.

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Q I'll get a copy of that for you.

MR. CLEMENT: Let's mark as Miller Exhibit 20 a copy of a -- the Baigent article Bates numbers 3130228 through 0239.

(Miller Deposition Exhibit 20 was marked for identification and attached to the transcript.)

BY MR. CLEMENT:

Q Dr. Miller, we put before you as Miller Exhibit 20 a copy of the Baigent article; right?

A I have that, yes.

Q And that's something you've seen before; right?

A Yes.

Q And that's something you had attached as an exhibit to your declaration?

A Correct.

Q It wasn't within the file history of any patent; right?

A I would have to check that.

Q Would you consider this to be -- actually, I guess, would you consider this to be extrinsic evidence?

A If it wasn't part of the prosecution history, then it would be.

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Q Did you find this article or was this something counsel provided to you?
A I've known about this article for years.
Q Again, did you find this article or was this something that counsel provided to you for purposes --
A I --
Q -- of drafting your declaration?
A I actually think I may have brought this article up --
Q Okay.
A -- to their attention.
Q And it says -- a 2005 article?
A I believe that's the date.
Q And where in this article does it define or talk about what a substantial increase is for LDL-C?
MR. KENNEDY: Objection to form.
THE WITNESS: Yeah, I'm not sure that that is defined in this article. The point of bringing this article was to show that as LDL increases, the risk for cardiovascular events also increases.
BY MR. CLEMENT:

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Q Okay. But it doesn't say anything about your 5 or 6 percent number; correct?
A I'm not sure that it was put in the context of the 5 to 6 percent. In fact, the -- the -- the -- the way this is read is a POSA would understand that for every increase in LDL there was a corresponding increase in cardiovascular risk, and that's shown in the paper in Figure 3.
Q I went through it and didn't see anything about 5 or 6 percent. And, I guess, if you had seen it, you would have put it in there, or do you want to take some time to take a look through it and see if you see anything, or you don't think it's there?
A Well, again, I don't -- I don't put this paper within the context of 5 to 6 percent. I put it in context of the preceding sentence which says, A POSA would understand that for every increase in LDL there is a corresponding increase in cardiovascular risk, and that is shown in Figure 3.
Q Figure 3 doesn't say anything about 5 or 6 percent; right?
A Correct.
Q And, again, sitting here today, you

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don't -- you recall putting this paper in here for that -- support of that statement but not in support of your opinion that substantial increase means 5 or 6 percent; right?
A Again, it's really the totality of data that I'm looking at. I'm looking at -- I'm considering all of the -- all of the evidence whether it's based on the specification or based on the prosecution history or even here some of the extrinsic evidence that this -- this statement is based on the totality of evidence that I have.
Q Okay. But, again, do you recall, sitting here today, any statement in this -- and I understand you're looking at the totality of the evidence. I just want to know for purposes of my small mind is there anything in here that says substantial increase should be 5 or 6 percent?
A And -- and as I pointed out before, the -- the sentence specifically talks about the increase in LDL. There was a corresponding increase in cardiovascular risk.
So if you have a 5 or a 10 percent increase in LDL, then you're going to have an increase in cardiovascular risk.
Q It says for every increase. So if you

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have a 1 percent, you have an increase; right?
A Correct.
Q And the Baigent article, that's not mentioned anywhere in the patent; right?
A I'd have to go through all those patents, but I'm not sure.
Q And then finally you rely on the ATP guidelines, right, for your -- explain that to decrease LDL-C by 6 percent, you double the dose of the statin; right?
A Yes, if I could refer back to the ATP III?
Q Sure, if you have that, I'll get mine.
A Yes.
Q Okay. Where are you looking at?
A I'm looking at Bates 0098.
Q Okay. And specifically where?
A Specifically on the first paragraph, in the middle of the paragraph, For example, the dose of a statin may be doubled at each visit to achieve an additional 6 to 7 percent LDL lowering with each dose titration.
Q Okay. That's referring to a lowering, right, a reduction?
A And the converse is also true.

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Q I'm asking does that refer to a lowering.
A That is correct.
Q And the patent refers to an increase; right?
A Yes.
Q I don't see the word "increase" in here at all, do you?
A No, but as I said it is -- it is -- converse is -- also holds.
Q That's what you say, but I didn't see it in that article. Did you?
A No, but you would see it in the Baigent article where you see that association quite well.
And that gets back to the point if you look at Figure 3 of this relationship between LDL and coronary disease.
Q One second. I've got to find my page. I'm sorry. Okay. Go ahead. Sorry.
A And -- and, so, what -- what has been established -- what we had known for many years is that as you go up in this association, as -- for every LDL increase, there is an increased risk of events. Conversely as you reduce LDL you also have a similar reduction in coronary events.

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So both directions work.
Q But Baigent doesn't mention anything about the 5 or 6 percent or rule of six at all; right?
A Again, we're looking at the totality of evidence which puts this -- pieces all -- this information -- puts it together.
Q Is this rule of six that you're talking about or the 5 or 6 percent number for substantial increase in LDL-C mentioned within the '728 patent specification?
A I would have to look at the patent specification --
Q Go ahead.
A -- to see if that's specifically mentioned.
Q You didn't cite to anything, right, in your declaration?
MR. KENNEDY: Objection to form.
THE WITNESS: (Reviews document.)
There was a mention of specification of LDL.
BY MR. CLEMENT:
Q Where are you?
A Let me see what page. Column 5 under

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D.
Q All right. But no mention of substantial increase; right?
A No. It talks about 5 percent increase -- less than 5 percent.
Q Talks about ten, 50, 20, 30, 35 -- it talks about all of them; right?
A Right. But, again, as I -- as I pointed out 5 to 6 percent would be the threshold by which we would consider adjustment of therapy and -- and, yes, so 10 percent for sure, 20 percent and 30 percent and higher levels of course, but 5 percent is that lower threshold limit.
Q Right.
But it doesn't say that's a substantial increase; right? It just mentions 5 percent; correct?
A Correct. And, again, looking at the totality of evidence in the prosecution history as part of the intrinsic evidence, so all of these are pieces that when put together provides, I think --
Q Did you cite to column 5, lines 37 to 46 in any of your declarations of the '728 patent

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in support of your understanding of the term "substantial increase"?
A I don't know if I -- if I did, but now that I'm reviewing the specifications, I see it here. I think it's, again, part of the -- of the history.
Q So is there anywhere in this patent that says substantial and gives a description that substantial increase in LDL-C means 5 or 6 percent other than what you just pointed me to?
A Yeah, it -- the 5 to 6 percent is a well-recognized number that we would derive as clinically meaningful in order to determine whether or not we might consider altering a patient's therapy.
Q Is your rule of six mentioned in the patent?
A That is -- I'm not sure if it's mentioned in the patent, but it is part of my declaration.
Q I understand it's part of your declaration. I'm asking if it's in the patent.
A I don't know if it's in the patent.
Q Is doubling the dose of a statin in the patent?

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A I don't know if it's in the patent.
Q Wouldn't doubling the dose of a statin be some sort of a lipid -- additional lipid-lowering therapy?
MR. KENNEDY: Objection to form.
THE WITNESS: Again, the focus here was to evaluate and treat patients with very high triglycerides. And the focus is lowering triglycerides. The focus wasn't to specifically also lower LDL. It was to lower triglycerides.
By the way, this medication seemed to not raise LDL compared to other medications that lowered very high triglyceride and did raise LDL. This did not do that.
BY MR. CLEMENT:
Q Understood.
But is there anything in the patent that talks about -- that you should double the dose of statins to figure out what substantial decrease in LDL means?
A I'm not sure.
Q Even doubling the dose of a statin, that would be additional lipid-altering therapy; correct?
A Yes. Again, I'm not sure that's

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relayed in the patent.
MR. CLEMENT: Okay. Why don't we take a break.
MR. KENNEDY: Okay.
THE VIDEOGRAPHER: The time is 3:28 p.m. We're going off the record.
(Recess -- 3:28 p.m.)
(After recess -- 3:43 p.m.)
THE VIDEOGRAPHER: The time is 3:43 p.m. We're back on the record.
Please proceed, Counsel.
MR. CLEMENT: Okay. Dr. Miller, thank you very much for your time today. At this point in time, we have no further questions.
MR. KENNEDY: Amarin has no questions for you at this time.
I would like to designate the transcript highest level of confidentiality because I think some internal documents were marked. We can talk at some point about, you know, limiting the designation, but I would like to make that designation.
I would like to reserve the witness' right to read and sign the transcript, then I think we're done.

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MR. CLEMENT: Sounds great. Thank you.
THE VIDEOGRAPHER: The time is 3:44 p.m. This concludes today's deposition given by Dr. Michael Miller. We are now off the record.

(Signature having not been waived, the Videotaped Deposition of MICHAEL MILLER, M.D., ended at 3:44 p.m.)

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CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Dana C. Ryan, Registered Professional Reporter, Certified Realtime Reporter, the officer before whom the foregoing proceedings were taken do hereby certify that the foregoing transcript is a true and correct record to the best of my ability of the proceedings; that said proceedings were taken by me stenographically and thereafter reduced to typewriting under my supervision; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 28th day of February 2018.

My Commission expires:
July 15, 2020

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E R R A T A S H E E T

IN RE: AMARIN PHARMA, INC., et al. v. WEST-WARD PHARMACEUTICALS CORP., et al.

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PAGE LINE CORRECTION AND REASON

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ACKNOWLEDGMENT OF DEPONENT

I, Michael Miller, M.D., do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me and any corrections appear on the attached Errata sheet signed by me.

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ERRATA SHEET

IN RE: AMARIN PHARMA, INC., et al. v. WEST-WARD PHARMACEUTICALS CORP., et al.

RETURN BY: _____

PAGE	LINE	CORRECTION AND REASON
41	18	"eicosapentaenoic" to "eicosapentaenoate" / Transcription Error
53	17	"eicosapentaenoic" to "eicosapentaenoate" / Transcription Error
54	5	"proceeded" to " preceded" / Transcription Error
56	7	"shown" to "known" / Transcription Error
58	13	"Heartland" to "Heart, Lung, and" / Transcription Error
99	10	"concur" to "refer" / Transcription Error
109	5	"simulation" to "scintillation" / Transcription Error
128	1	"microprotein" to "lipoprotein" / Transcription Error
131	8	"low" to "lowering" / Transcription Error
172	25	"eicosapentaenoic" to "eicosapentaenoate" / Transcription Error
194	14	"Amarin at 2 grams a day and Amarin 101" to "AMR 101 at 2 grams a day and AMR 101" / Transcription Error
194	18	"Amarin 101 is Amarin 101" to "AMR 101 is AMR 101" / Transcription Error
195	3-4	"Amarin 101" to "AMR 101" / Transcription Error
195	6	"Amarin 101" to "AMR 101" / Transcription Error
200	4	"who" to "two" / Transcription Error
200	20	"total unsaturated" to "total and saturated" / Transcription Error
222	25	"eicosapentaenoic" to "eicosapentaenoate" / Transcription Error
227	4	"were not" to "were" / Transcription Error
228	20	"eicosapentaenoic" to "eicosapentaenoate" / Transcription Error
251	10	"Amarin 101" to "AMR 101" / Transcription Error

(DATE) 3/20/18 (SIGNATURE)

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ACKNOWLEDGMENT OF DEPONENT

I, Michael Miller, M.D., do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me and any corrections appear on the attached Errata sheet signed by me.

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